Drug candidates by Disease Area

GEMSEKI
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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
Cardiology	GEM133	Myocardial protection by cardiac arrest temporally	Open heart surgery	Intra-coronary infusion	Others	Launched	GEM133 is a novel warm cardioplegic solution which in mixture with patient's oxygenated blood can produce effective and sustained cardiac arrest by a single dose 400ml. In addition, it has the following advantages; virtually unlimited aortic cross-clamp time, unassisted resumption of the cardiac rhythm, no ischemic and /or reperfusion injury, no need for cardiotonic support in the immediate postoperative period.
	GEM161	Restoration of autophagy and reduction of inflammation	Cardiovascular and Metabolic disorder	Oral	Oligo-saccharides	Phase 2b/3 ready	A novel derivative (pat. pend.) of hydroxypropyl-α-cyclodextrin (HPαCD) that down-regulates the PI-system by controlling serum phospholipids and, thereby, reduces endocytosis. βCDs have been shown to be effective in vivo against atherosclerosis (AS), NAFLD, but can cause permanent hearing loss (not applicable to αCDs). Oral αCD is clinically effective against metabolic syndrome, but has low and variable bioavailability. 505(b)(2) is applicable.
	GEM182	Direct renin inhibitor (DRI)	Hypertension (HP), diabetic nephropathy (DKD), chronic hemodialysis, heart failure	Oral	Small molecule	HP : Phase 2 ready DKD: Phase 2 completion	A 2nd generation DRI with better renoprotective effects than ACEi/ARB. Better hypotensive effects than aliskiren is expected due to higher BA, less variability and no food effect following oral treatment. Prolonged renal localization, blood pressure independent renoprotection and positive effect on renal blood flow are evidenced by DRIs. In clinical trials of GEM182 in T2DM patients with microalbuminuria, dose-dependent UACR reduction and increases in remission rate from albuminuria were also seen. This compound have been developed as mono-therapy (not combined with ACEi/ARB). Therefore, GEM182 has no safety issues seen in aliskiren's ALTITUDE trial due to RAS dual blockade. Injectable formulation is also developed (ref. GEM183). Licensing discussion is available except for China.
	GEM173	Anti-fibrotic effects	Anti-Fibrotic-Treatment of patients after Aortic-Valve-Implantation	Oral	Small molecule	Phase 1	Combination of marketed small molecule drugs to exert anti-fibrotic effects. A novel anti-fibrotic therapy is supposed to reduce progression of fibrosis and stabilize heart functioning. Myocardial fibrosis was found to independently predict cardiovascular mortality after AVI. Patent application has been made globally. Discussions are available for Japanese companies and Chinese companies.
	GEM247	Activation of progenitor and endothelial progenitor cells	Chronic limb threatening ischemia	Injection and device	Regenerative therapy	Clinical	Regenerative therapy for vascular disease promotes new vessel growth. Excellent clinical results include pain relief, wound healing, hemodynamic improvement, new collaterals visible on angiography, biochemical support for mechanism of action, and limb salvage.

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	GEM061	Curcumin-releasing topical formulation (sustained release for about 24 hours)	Please refer to Note	Topical	Small molecule	Preclinical	Indication: Osteoarthritis, CV disease, chronic inflammatory disease, vascular disease (Sickle Cell) Note: Curcumin's utility: chronic pain, chronic inflammatory conditions such as osteoarthritis, vascular disease such as Sickle Cell and diabetes. This formulation addresses limitations of the poor oral bioavailability of curcumin. Preclinical efficacy demonstrated in an rodent arthritis model and a rodent diabetes model.
	GEM124	Improves endothelial cell function and cellular fluidity. Antiatherosclerotic, anti-inflammatory, anti-fibrotic, fat-targeting composition	1) Atherosclerosis (#) 2) Treatment of NASH (Stage F2-F3) Fibrosis with no worsening of fibrosis.	Oral	Small molecule	Preclinical	1) Developed to target vulnerable, high risk plaques while also reducing LDL cholesterol, increasing HDL cholesterol and reducing Triglycerides. (#) Future indications: primary prevention of Heart Attack, Stroke and Death and Secondary Prevention of Myocardial Infarction in Europe. US Patent to treat Atherosclerosis is valid until 2035. 2) Concurrently being developed to treat liver inflammation, fibrosis and fat accumulation while also reducing LDL cholesterol and Triglycerides. *May be used in combination with other drugs, such as Intercept's Ocaliva that increases Triglycerides or Gilead's NASH candidate that increases LDL cholesterol.
	GEM183	Direct renin inhibitor (DRI)	Blood pressure control and/or prevention of heart failure in patients with chronic hemodialysis	i.v.	Small molecule	Preclinical	Injectable formulation of GEM182 (oral formulation in phase-2b), is also being developed for potential use for better blood pressure control and/or prevention of heart failure by chronic intravenous treatment three times per week via vascular access established in patients with chronic hemodialysis. Renin inhibitor may be suitable for such patients who often exhibit hyperreninemia potentially due to residual function of juxtaglomerular apparatus as well as reduced renal blood flow after start of the hemodialysis. Although dialysis patients are mostly unavoidable from hypertension, no optimal treatment has been available yet. GEM183 can fulfill such rapid growing huge unmet medical needs. Licensing discussion is available except for China.

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	GEM203	FXR agonist and 5-HTR2A antagonist	NAFLD, Type 2 diabetes, obesity, dyslipidemia and hypertension	Oral	Small molecule	Preclinical	First in class single molecule having both FXR agonistic and 5-HTR2A antagonistic actions. In DIO mice, GEM203 reduced hyperglycemia, hyperinsulinemia, insulin resistance and liver lipid contents to similar or greater extent vs metformin. GEM203 reduced the body excess weight while metformin did not. In NASH model mice, GEM203 reduced liver excess weight, TG and TC contents, plasma ALT and AST, inflammation and collagen gene expression in the liver. Strong IP portfolio with long expiry dates granted in major markets.
	GEM171	ARNT regulation	Fibrosis in kidney, heart and liver	Oral / or gene therapy	Small molecule or morpho-linos	Discovery – Preclinical	No effective therapy for fibrosis is available yet. ARNT homodimerizartion attenuates fibrosis progression and induces regenerative cellular responses. Several mechanisms of action and potential drugs were identified, which show inhibition of ARNT degradation or activation of ARNT expression. PCT patent application filed. Discussions are available for Japanese companies and Chinese companies.
	GEM251	Antisense oligo nucleotide (ASO) suppressing the expression of human p53 gene	AKI(acute kidney injury), Heart failure, Stroke	i.v.	Nucleic acid	Discovery/ Preclinical	Suppression of p53 expression may reduce the tissue damage and enhance tissue repair in several disease conditions. It inhibits p53 expression better than the competitor compound in cultured cell, and is therefore expected to be highly effective in clinical practice.
CNS	GEM241	Analyzer of EEG algorithm by AI	Prediction of seizures in epilepsy patients	Ear wearable	Medical device	On Market	・A personalized ear-wearable non-invasive small medical device which detects changes in EEG pattern by AI algorithm that alerts seizure minimum one minute before it occurs to patients and caregivers. ・It records brain activities through the ear canal and uses Big Data. ・By predicting the seizure before it occurs, the device will prevent accidents and reduce injuries, emergencies, and deaths. ・It reduces emotional impact such as anxiety/depression and increases de quality of life. ・Big Data treatment can help doctors and medical society to better understand the illness and perform patients' follow-up.
	GEM160	Restoration of autophagy and reduction of inflammation	Neuro-degenerative diseases	Oral, Intra-thecal	Oligo-saccharides	Phase 2b/3 ready	A novel derivative (pat. pend.) of hydroxypropyl-α-cyclodextrin (HPαCD) that down-regulates serum phospholipids and prevents aging cells from accumulating Aβ/tau (AD), α-syn (PD), myelin (MS), mHTT (HD), SOD1 (ALS), ... βCDs were effective in vivo against AD and PD, but development was abandoned (except for NPC) due to the risk of permanent hearing loss (not applicable to αCDs). In the US, αCD is generally recognized as safe (GRAS) for oral use; in the EU, αCDs are approved for oral and parenteral use. 505(b)(2) is applicable.

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	GEM089	Inhibition of pro-cytokines, enhancement of growth factor PDGF	Alzheimer's disease and Vascular dementia	Topical	Botanical	Phase 2	Small molecules from soybean extract. MOA is different from Tau and Amyloid mechanisms. Effective in $AlCl_3$ induced Alzheimer-like dementia model and bilateral common carotid artery occlusion induced vascular dementia model. In Phase 2 study, MMSE and ADAS-Cog for patients without any dementia medication indicated that 70-85% patients improved at weeks 4 and 12.
	GEM131	Matrix metalloproteinase-2 (MMP-2) and MMP-9 inhibitor	Neuropathic pain and Amyotrophic lateral sclerosis (ALS)	Oral	Small molecule	Close to IND ready *	Pain: GEM131 can block inflammatory responses at the site of nerve damage and has been shown to be efficacious in 4 different rodent models of neuropathic pain (spinal nerve ligation, chronic constriction injury of the infraorbital nerve, morphine withdrawal and thermal injury). ALS: Elevated levels of MMP-2 and-9 have been found in the skin and blood of people with ALS. Significantly improved larval locomotion in both the TDP-43 and SOD1 larvae models in Drosophila. Exhibits good oral bioavailability. *: Final stages of completion of IND enabling studies for both neuropathic pain & ALS
	GEM149	PKC modulator	Alzheimer disease	Oral, Intranasal	Small molecule	Phase 1	Up-regulates production of α-secretase which cleaves the amyloid precursor protein, APP, into a harmless soluble form, sAPP-α, which is non-neurotoxic and limits the formation of amyloid plaques.
	GEM035	An anti-ENO1 antibody	Immune diseases, Various cancers	s.c.	Protein	US FDA IND cleared	GEM035 is a humanized antibody against unique ENO1 target. This therapeutic antibody is first-in-class to target inflammatory macrophage and demonstrates efficacy in animal models of MS, IPF, and IBD. It also showed efficacy in animal models of lung, pancreatic, and prostate cancer, most likely by targeting tumor associated macrophage (TAM). GEM035 may be developed for treatment of COVID-19 induced ARDS based on its capability to suppress macrophage related immune response. GEM035 has a worldwide patent protection. US IND of GEM035 is approved and active now for treating MS.
	GEM252	Cultured skin stem cells autografts	Spinal cord injury	Transplant into spinal cord (Autologus)	Cell therapy	Clinical application finished	The Skin stem cells cultured in serum-free medium express Nestin, CD73 and GDNF. They showed no tumorigenicity in carcinogenicity test. Autologous transplantation for patients with spinal cord injury was performed with intraspinal administration via lumbar puncture. A most aggressive result was a case which a man with 2.5years paralysis of lower limbs by Th3 site injury, who recovered to the level of walking after receiving 2 times.

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	GEM172	Activation of multiple sulfatase	Multiple Sulfatase Deficiency	Oral / or injection	Small molecule	Preclinical – Phase 1 study in preparation	No effective treatment for the rare disease MSD is available. Combination of marketed drugs increase the activity of multiple sulfatases and significantly reduce toxic glycosaminoglycans in MSD fibroblast cell lines. Priority patent, which lead to global application, has been filed. Discussions are available for Japanese companies and Chinese companies
	GEM034	Derivative of neuroprotective protein	Stroke, Huntington chorea, Schizophrenia and PTSD	i.v.	Peptide	Preclinical	A cell-permeable recombinant peptide. Can cross the blood-brain barrier, is resistant to degradation, and can bind constitutively to its substrates. Significantly reduces brain damage in rodent stroke model. Expected to be treated after stroke without diagnosis of stroke type before dosing.
	GEM091	Prevention of protein aggregation via increased intracellular ATP and increase of expression of tyrosine hydroxylase (TH)	Parkinson's disease	Oral Nasal	Small molecule	Preclinical	New treatment for Parkinson's disease.GEM091 increases intracellular ATP level and ATP is reported to boost protein solubility. GEM091 increases TH expression and dopamine production, reverses paraquat induced PD symptoms and improves behavior of 6-OHDA treated mice.
	GEM100	mGluR5 negative allosteric modulator	Depression and Movement disorder	Intra-nasal	Peptide	Preclinical	mGLuR5 leader peptide was discovered and in vivo efficacy confirmed. GEM100 specifically increases locomotor activity in rats, with no effects on behavior.
	GEM101	GABA-A negative allosteric modulator and an inhibitor of α2δ subunit of voltage-gated calcium channels	Depression and PTSD	Intra-nasal	Peptide	Preclinical	Exhibited both rapid and long-lasting anxiolytic and antidepressant activity in vivo animal models. Stable in vivo and crosses the blood-brain barrier. No adverse effects typical for standard of care drugs (No sedation, No tolerance, No cognitive impairment, No addiction potential)
	GEM119	Inactivation of end-product of lipid peroxidation	Cerebral infarction	i.v.	Small molecule	Preclinical	· Showed more potent 4-hydroxynonenal - quenching activity compared with carnosine or histidine hydrazide (HH) at 30min incubation. · GEM119 (ip administration) rescued the hippocampal CA1 cell death of transient cerebral ischemia model of Mongolian gerbil whereas HH did not.

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	GEM143	CB1, CB2, 5-HT1a	Multiple Sclerosis (MS), Opioid addiction, Chemotherapy induced Peripheral Neuropathic Pain (CIPNP), and Epilepsy	Oral	Small molecule	Preclinical	GEM143 is a nanoencapsulation of the API in biodegradable polymer nanospheres for improved oral bioavailability. MS: The API has multiple actions on key molecular neuroinflammation and neurodegeneration targets, with highly effective in vitro and in vivo bioactivities. Opioid addiction: The API is not an opioid and has been shown to alleviate cue-induced opioid addiction behaviors and allosterically modulate the μ and δ-opioid receptors. CIPNP: Nanoencapsulation is being used to protect the API during the stomach passage. Epilepsy: The API is an effective anti-convulsant with a specificity more comparable to drugs clinically effective in major seizures.
	GEM177	BOTOX Biosimilar	Refer to Note	Injection	Protein	Preclinical	Equivalent efficacy and similar safety profile (for biosimilar for Allergan Botox) Manufacturing using plant-derived mediums Indication - Therapeutic applications: strabismus, cerebral palsy, cervical dystonia, neurogenic bladder, migraine, facial spasm, blepharo spasm - Aesthetic application: all wrinkles produced due to persistent muscular contractions, square jaw reduction, hyperhidrosis
	GEM257	Promotion of Axon regeneration	Disease with nerve damage	injection	Protein	Preclinical	GEM257 accelerated the rate of axonal regeneration (in vitro and in vivo), thereby restoring sensory function and tibialis anterior muscle function in vivo. GEM257 can use as a nerve regeneration drug (local injection) for peripheral and central nerve damage and nerve regeneration inducer at combination with nerve regeneration inducing materials and regenerative medicine using autologous cells.
	GEM248	Antisense oligo nucleotide (ASO) suppressing the expression of human p53 gene	ALS(C9orf72)	Intramedullary	Nucleic acid	Discovery	Suppression of p53 expression may reduce the tissue damage and enhance tissue repair in several disease conditions. It inhibits p53 expression better than the competitor compound in cultured cell, and is therefore expected to be highly effective in clinical practice.
	GEM210	TFEB activation	Alzheimer's and Parkinson's disease	Oral	Small molecule	Lead optimization stage	A new mechanism of action (and first-in-class oral form) to accelerate the degradation of neurotoxic proteins by autophagy. mTOR independent autophagy targets the removal of multiple misfolded proteins (e.g. beta-amyloid, tau) In several neurodegenerative diseases, mTOR/Transcriptional factor EB (TFEB) and therefore autophagy is dysfunctional. GEM210 increases TFEB translocation to the nucleus and enhances autophagy.

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Dermatosis	GEM127	Antibiotic	Primary and secondary skin infection - Impetigo, Folliculitis, Furunculosis (human use)	Topical	Small molecule	Launched	· The first product on the market that combines the therapeutic benefits of a marketed antibiotic with an innovative transparent film-forming and bioadhesive delivery technology. · When applied to the lesion, generates a film that acts as a bioadhesive sustained release matrix, maintaining the optimum concentration of antibiotic in the skin for a period of 6-8 hours. · The bioadhesive film generated prevents the removal of the antibiotic from the lesion and acts as a protective dressing that prevents infection spreading.
	GEM130	Antiviral	Infections caused by herpes simplex virus in face and lip	Topical	Small molecule	Launched	· First cold sore product on the market that combines the therapeutic benefits of an antiviral with an innovative transparent bioadhesive film. · When applied to the lesion, generates a transparent film that acts as a bioadhesive sustained matrix release that improves product bioavailability while promotes itching reduction and wound healing. · Indicated for the topical treatment of symptoms (tingling, burning, discomfort) of recurrent herpes labialis caused by herpes simplex virus (VHS).
	GEM204	Multi-molecular targeting including the Wnt/β-catenin pathway	Hair loss, Androgenetic Alopecia, Telogen effluvium, Senescent Alopecia	Topical and/or oral	Plant extracts	Commercial	GEM204 is a comprehensive solution for the treatment of hair loss, targeting more than 21 hair regulating molecular pathways to promote hair growth and inhibit hair loss. Market approval and full scientific dossier available with clinical trials in women and men of all hair loss patterns, hair types and skin types.
	GEM235	Mineral sunscreen powder	Sunscreen	Topical	Natural ingredient	Commercial	GEM235 is an easy-to-use brush applicator, filled with an effective mineral powder with SPF 50. The 100% natural formula makes GEM235 safe to use on rash-prone skin, eczema, allergy-prone skin and sensitive skin.
	GEM198	A fixed dose combination of melatonin and resveratrol.	Alopecia / Hair Loss	Topical	Small molecule	Pre registration	Resveratrol stimulates hair growth by decreasing prostaglandin D2 (PGD2) and increasing prostaglandin E2 (PGE2). Melatonin is a neurohormone involved in multiple physiological processes underlying circadian rhythm. Due to its antioxidant properties, melatonin has remarkable protective effects on cells and anti-apoptotic properties. Hence the association between melatonin and hair growth. The effect of melatonin on hair growth may be moderated by an interaction with androgens and estrogens and their receptors. Results from a clinical study demonstrated that GEM198 was more effective at stopping hair loss than Minoxidil. US patent issued, and international patents have been filed.

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	GEM199	A fixed dose combination of Minoxidil, resveratrol and melatonin.	Alopecia / Hair Loss	Topical	Small molecule	Pre registration	Minoxidil is a potassium channel blocker that prevents hair loss by improving blood flow to the hair follicle. It also suppresses androgen receptor function and stimulates the production of prostaglandins. Resveratrol stimulates hair growth by decreasing prostaglandin D2 (PGD2) and increasing prostaglandin E2 (PGE2). Melatonin is a neurohormone involved in multiple physiological processes underlying circadian rhythm. Due to its antioxidant properties, melatonin has remarkable protective effects on cells and anti-apoptotic properties. Hence the association between melatonin and hair growth. The effect of melatonin on hair growth may be moderated by an interaction with androgens and estrogens and their receptors. Results from a clinical study demonstrated that GEM199 was more effective at stopping hair loss than Minoxidil. US patent issued, and international patents have been filed.
	GEM197	A fixed dose combination of minoxidil, finasteride and latanoprost.	Androgenetic alopecia	Topical	Small molecule	Phase 3	Minoxidil is a potassium channel blocker that prevents hair loss by improving blood flow to the hair follicle. It also suppresses androgen receptor function and stimulates the production of prostaglandins. Finasteride is a 5 alpha reductase inhibitor that reduces the conversion of testosterone to dihydrotestosterone (DHT), which in turn reduces the binding of DHT to the androgen receptor, thereby reducing the miniaturization of the hair follicle. Finasteride also upregulates SULT1A1, which activates the pro-drug of minoxidil into its active form - minoxidil sulfate Latanoprost is a prostaglandin analogue that has a positive stimulatory effect on the hair follicle and induces the conversion from telogen to anagen phase in the hair growth cycle. Results from a completed phase 2 study have demonstrated that GEM197 is a well-tolerated, once a day, topical fixed dose triple combination therapy that stimulates new hair growth and prevents further hair loss for the treatment of androgenetic alopecia in men 24-65 years old. The FDA has given a roadmap to start a Phase 3 clinical trial under 505(b)(2). International patents have been issued.

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	GEM207	A3 adenosine receptor (A3AR) agonist	Rheumatoid arthritis (RA), Psoriasis	Oral	Small molecule	Phase 3	・A3AR is highly expressed in inflammatory and cancer cells. Specific agonists of A3AR induce apoptosis of inflammatory cells but not normal cells. ・Very good safety profile as 1st line therapy. ・In the pahse-2b study (monotherapy vs placebo) for12 weeks in naive RA patients, the endpoint was achieved. ・In the pahse-2/3 study (monotherapy vs placebo) in moderate to severe psoriasis patients, it did not meet the primary endpoint at 12 weeks, but at 32 week the improvement of PASI score was significant vs at 16 week. ・A phase-3 study (vs MTX) in moderate to severe RA and a phase-3 study (vs apremilast) are ongoing.
	GEM001	TRPV-1 agonist	Rheumatoid arthritis, Please refer to Note	Oral	Small molecule	Phase 2a	Updated on January 11, 2019 Potently inhibits TNF-a production by oral administration. Discontinued development for RA. Available for repositioning. Possible indications: Neuropathic pain, Crohn's disease, Systemic lupus erythematosus, Cachexia, Acute infectious disease, Allergy, Pyrexia, Anemia, Diabetes, Diseases related TNF-α (Colitis, Psoriasis ets.)
	GEM057	Increase hair follicle ATP and delay senescence of dermal papilla cells	Alopecia	Topical	Small molecule	Phase 2	Boosts the ATP of human follicle dermal papilla cells, thereby slowing down the aging speed and prolonging hair cycle. No side effects and shorter time to observe efficacy Human trial (Androgenetic Alopecia): significantly improved 37.5% vs 0% (placebo) during 2 months. Phase 2 (Female pattern hair loss) resulted in earlier improvement of hair loss and patient responses than minoxidil.
	GEM058	Increase cellular ATP and promote wound healing	Diabetes foot ulcer	Topical	Small molecule	Phase 2 completed	Reducing inflammation of endothelial cells of blood vessels. Increasing cellular ATP and speeding up the healing of wounds by promoting the migration of epithelia cells in the skin of wounds. The arrangement of actin which is essential for cell migration is ATP dependent. Applicable to all kind of wound and low cost treatment. Phase 2: The estimated complete closure rate is around 60% (vs placebo 30%)

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	GEM129	Immuno-modulator	Anogenital warts, Actinic keratosis, Basal cell carcinoma	Topical	Small molecule	Phase 2	· The first product on the market that combines the therapeutic benefits of a marketed immunomodulator with an innovative transparent bioadhesive film. · When applied to the lesion, generates a transparent bioadhesive film, which acts as a reservoir or matrix release and reduces the local reactions and increases the permanence of the product in the action site. · The results of non-clinical studies demonstrate that GEM129 has a better safety profile with an equivalent efficacy than its reference product. Clinical studies on-going.
	GEM233	Inhibition of pro-cytokines, enhancement of growth factor PDGF	Diabetic foot and leg ulcers	Topical	Botanical	Phase-2 Completed	Small molecules from soybean extract. MOA facilitates multiple phases at molecular levels of wound healing processes. Effective in STZ induced diabetic wound model and cell migration quality control. In Phase 2 study, ulcer complete closure rate up to 12 weeks is 32.7% in GEM233 group vs 15.4% in placebo group. Subjects in the GEM233 group had an average of 73±2.9 days to achieve ≥ 90% reduction in target ulcer size.
	GEM155	FPR2-specific ligand	Atopic dermatitis/Psoriasis, Dry eye disease, IBD (Inflammatory bowel disease), Asthma, Rheumatoid arthritis	Topical, Eye drop, s.c.	Peptide	Phase 1	GEM155 is a small (7mer) lipidated peptide ligand for pro-resolving receptor FPR2 (N-formyl peptide receptor 2) involved in regulation of innate immune system and inhibition of ILC2 function (adaptive immune system). It also has anti-microbial effect for pathogenic bacteria through fusion with functional moiety. Efficacy is seen in animal models for the indications. CMC study is almost done. Toxicity study for topical usage and subcutaneous injection is going-on. Formulation for topical use is almost finished.
	GEM003	Selective glucocorticoid receptor agonist	RA/OA, Please refer to Note	Local	Small molecule	Preclinical	Updated on January 11, 2019 Expected to reduce unfavorable responses of glucocorticoids by selectivity of action (transrepression>transactivation) Discontinued development for RA/OA. Available for repositioning. Possible indications: Atopic dermatitis, Psoriasis, Asthma, COPD, Inflammatory bowel disease etc.
	GEM039	Antifungal	Onychomycosis	Topical	Small molecule	Preclinical	Novel and unique topical formulation of Terbenafine with exceptional permeation (40 fold) across the human nail. Potential for OTC or RX introduction: minimal development timeline

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	GEM060	Nitric Oxide-releasing topical formulation (sustained release for over 48 hours)	Please refer to Note	Topical	Small molecule	Preclinical	Indication: Acne, Atopic Dermatitis, Fungal diseases, Wound healing, Chronic rhinosinusitis, Diabetic foot ulcers, Raynaud's Phenomenon, Middle-ear infections, Erectile dysfunction, Others Note: NO function: Regulation of the vasculature (vasodilatory), broad spectrum antimicrobial activity, anti-inflammatory, anti-oxidant, wound healing, skin cell maturation and survival etc. Human POC already shown with NO in onychomycosis, genital warts, moscullum contagiosum, pulmonary hypertension, acne, atopic dermatitis (preliminary); animal POC demonstrated in over 20 peer-reviewed papers. Efficacy also demonstrated in preclinical model of erectile dysfunction. This formulation addresses many limitations of NO by providing cost-effective, shelf-stable formulation that provides sustained release of NO.
	GEM062	Anandamide(AEA)-releasing topical formulation (sustained release for about 24 hours)	Cutaneous Lupus, (and other autoimmune/ inflammatory skin conditions)	Topical	Small molecule	Preclinical	Tissue imaging to demonstrate efficient penetration and controlled release of AEA from AEA-loaded GEM062. Efficacy of AEA-loaded GEM062 in treating cutaneous lesions in murine model of CLE has been demonstrated.
	GEM076	Galectin-12 inhibitor	Seborrheic dermatitis; Sebaceous hyperplasia	Transdermal	siRNA	Preclinical	A modified siRNA for suppressing gene expression of galectin-12 which is a lipid droplet protein and regulates lipid accumulation and lipolysis. The siRNA can reduce the lipid in sebocytes and adipocytes and shows good stability and selectivity to reduce the lipid accumulation through transdermal delivery in vivo.
	GEM090	Increase cellular ATP and promote wound healing	Epidermolysis bullosa (EB)	Topical	Small molecule	Preclinical	Increasing cellular ATP and speeding up the healing of wounds by promoting the migration of epithelia cells in the skin of wounds. Expected to shorten wound healing time and improve EB patients' QOL with a formulation optimized for EB treatment. Moreover, maybe reduces the risk of squamous cell carcinoma which is highly related to Dystrophic EB patients.
	GEM118	Suppression of TGF-b/Smad and related signaling	Systemic sclerosis	Oral	Small molecule	Preclinical	· Inhibited phosphorylation of Smad3 and expression of Col1a2, FN1 and CTGF stimulated by TGF-b in cultured human dermal fibroblasts. · Ameliorated bleomycin-induced skin fibrosis in both preventative and curative mouse model.
	GEM138	Biosimilar adalimumab	Same indications as adalimumab	i.v.	Antibody	Preclinical	Purified GEM138 is highly similar to adalimumab by SDS-PAGE. GEM138 and adalimumab show a similar response in a TNF-a ELISA assay. Plant-based technology (TGEM036) was applied for production of GEM138.

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	GEM153	Angiogenic peptide	Wound-care, Diabetic foot ulcer, Cosmetics	Topical	Peptide	Preclinical	Increases blood vessel formation (VEGFA/VEGFR1 expression ↑& cell proliferation/migration ↑). Boosts collagen synthesis at sub-nanomolar concentration (Wrinkle-care) & inhibits melanin synthesis (Whitening). Registered cosmetic ingredient.
	GEM154	Collagen-inducing peptide	Dermal filler, Cosmetics	Topical	Peptide	Preclinical	Laminin-derived peptide. Boosts collagen synthesis at sub-nanomolar concentration (Wrinkle-care) & inhibits melanin synthesis (Whitening). Registered cosmetic ingredient.
	GEM239	Activation of Treg and downregulating pro-inflammatory cytokines	Psoriasis, Please refer to Note	Oral	Small molecule	Human POC completed	Microbiomes are important for regulating human immune systems.GEM239 is a small molecule known as a gut microbial metabolite. It downregulates pro-inflammatory cytokines, and promotes differentiation of anti-inflammatory Treg cells. Human POC study in a small number of psoriasis patients has been done and significant treatment effects have been seen. FDA IND approved. Clinical trial starting in 30 patients. Potential indications may include psoriatic arthritis, rheumatoid arthritis, ankylosing spondulitis, Crohn's and colitis. Formulation-science has been applied.
	GEM250	Antisense oligo nucleotide (ASO) suppressing the expression of human p53 gene	Drug-induced alopecia	Topical	Nucleic acid	Discovery	Suppression of p53 expression may reduce the tissue damage and enhance tissue repair in several disease conditions. It inhibits p53 expression better than the competitor compound in cultured cell, and is therefore expected to be highly effective in clinical practice.
Diagnosis	GEM180	Contrasting	MRI Contrasting	i.v.	Nano particle	Phase 2	GEM180 is a MRI contrast medium which can detect more small liver lesion, compared to marketed product, because of the better contrast. Biopsy confirmed the number of small nodules by GEM180. GEM180 has better imaging results (higher percent signal intensity loss (PSIL) and better consistency) from CT001. So far no obvious severe adverse events seen. Comprehensive patent portfolio exist globally.
	GEM084	MRI contrast agent formulation	Diagnosis of bladder cancer	Topical (Intravesical)	Other	Phase 2 ready	New formulation consisting of iron and gadolinium for intravesical instillation.A pilot trial in humans provided evidence that the MRI contrast agent can be detected in the bladder wall. No treatment-related AEs were observed.
	GEM170	Improved PCR	Diagnostic for detection of Paratuberculosis in animals and potentially Crohn's disease in humans	in vitro	Others	POC obtained in animals	New and improved PCR diagnostic test for fast and early detection of Mycobacterium avium subspecies paratuberculosis (MAP). This method shows better performance than current ELISA as well as on current PCR tests. Diagnostic test for early MAP detection in domestic livestocks, exotic ruminations and human patients. Discussions are available for Japanese companies and Chinese companies. * Successfully tested in feces, blood, milk, sperm and tissue samples

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
Endocrinology	GEM092	Androgen receptor agonist	Hypogonadism	Oral (BID)	Small molecule	Received FDA tentative approval	A novel oral prodrug of testosterone that is designed to help restore normal testosterone levels in hypogonadal men. GEM092 was well tolerated and met the primary end-points in Phase 3 testing with twice daily dosing. Easy to use for patients and physicians to prescribe due to fixed doing regimen.
	GEM093	Androgen receptor agonist	Hypogonadism	Oral (QD)	Small molecule	Phase 2 completed	A novel next generation oral prodrug of testosterone with potential for once-daily oral dosing that has completed Phase 2 testing.
	GEM096	Progesterone receptor agonist	Recurrent preterm birth	Oral	Small molecule	Phase 2 completed	Potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. An end of Phase 2 meeting was completed with the FDA.
	GEM098	GnRH receptor antagonist	Endometriosis and Uterine fibroids	Oral	Small molecule	Phase 1	In Phase 1b, GEM098 showed dose-dependent suppression of LH, FSH and E2. The suppressive effects on E2 lasted up to 24 hrs and were more excellent when compared with the published phase 1 data of Elagolix in healthy premenopausal women. No serious adverse events were seen and well tolerated up to 320 mg QD.
	GEM072	Orally available somatostatin analogues	Metabolic syndromes, Acromegaly, Hyperprolactinemia etc.*	Oral	Protein	Preclinical	The technology and "know-how" to synthesize somatostatin analogues which will be more potent, more specific, stable and orally available have been established. A few analogues (at lead generation/optimization stage) with different combination of receptor selectivity and differential hormonal secretion inhibition properties are available. *: Congenital hyperinsulinism, insulinomas, glucagonomas
	GEM226	Anti-fibrin scFv with reteplase	Pathological Clots	i.v.	Antibody conjugated reteplase	Preclinical	GEM226 - can bind to human fibrin/crosslinked fibrin, but not to fibrinogen and bind to human fibrin under high concentration of fibrinogen. -GEM226 is stable in buffer at 4°C and alteplase showed similar enzyme kinetics to tPA substrate, also can dissolve clots effectively, accumulate at the clot in vivo and bind to human clots specifically -GEM226 has better PK profile in rat and shows better clot-dissolving effect than that of alteplase in MCAO mice model. -GEM226-treated MCAO stroke mice have better neurobehavior than the mice treated with alteplase
	GEM227	Octreotide with fatty acids bundles	carcinoid syndrome/ acromegaly	s.c.	Peptide conjugated fatty acid	Preclinical	GEM227 - can be produced in high quality and bind to HSA effectively. - Fatty acids bundle can effectively prolong serum half-life of octreotide and antiproliferative effect of GEM227 is similar to that of octreotide. - can effectively reduce serotonin level in xenograft mouse model.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
Gastroenterology	GEM196	Potassium-Competitive Acid Blocker (P-CAB)	Peptic ulcer	Oral	Small molecule	Phase 3	Phase 3 is ongoing. P-CABs are the best treatment with better and fater efficay for gastric acid-related gastrointestinal diseases such as gastric and duodenal ulcer, GERD, NERD, ZES and etc. GEM196 is a potentially best-in-class P-CAB - Faster clinical benefit in phase 2 study compared with Lansoprazole for duodenal ulcer treatment. - Rapid and high absorption, oral bioavailability in clinical study. - Lower toxicity and better PK, PD than TAK-438. - Acid stability- exempt acid protection - Longer lasting-higher concentration on target site - Less individual differences- isoenzyme CYP2C19 metabolism tiny dependence.
	GEM001	TRPV-1 agonist	Rheumatoid arthritis, Please refer to Note	Oral	Small molecule	Phase 2a	Potently inhibits TNF-a production by oral administration. Discontinued development for RA. Available for repositioning. Possible indications: Neuropathic pain, Crohn's disease, Systemic lupus erythematosus, Cachexia, Acute infectious disease, Allergy, Pyrexia, Anemia, Diabetes, Diseases related TNF-α (Colitis, Psoriasis ets.)
	GEM059	Recombinant Human Interleukin-1 Receptor Antagonist	Please refer to Note	IM	Protein	Phase 1	Indication: 1: Infection, as manifested by febrile neutropenia, in patients with malignancies receiving chemotherapy drugs. 2: Diarrhea in patients with malignancies receiving chemotherapy drugs. 3. Gout arthritis Note: The world's first multiorgan protection agent for tumor chemotherapy. Inhibits cell cycle progression of normal cells and renders them resistance to chemotherapy. No effects on tumor growth and their sensitivity to chemotherapy Phase 1 : No dose limiting toxicity, None of subjects presented grade 3 or above chemotherapy-induced neutropenia or diarrhea. Gout arthritis: Well tolerated and safe for patients who are restricted from NSAID, glucocorticoid, or colchicine.
	GEM187	Mesenchymal stem cell	Rheumatoid Arthritis (RA), Inflammatory Bowel Disease (IBD), COVID-19	Implant (allogenic)	Cell	IND	GEM187 is a fresh (non-frozen) human allogenic umbilical cord tissue derived mesenchymal stem cells (hUC-MSC) product. - Proprietary manufacturing process with no risk of contamination. - "Youngest" adult MSC with robust proliferation capacity. - Highly scalable to achieve enough cells. - Superior biological functions: optimal cell viability and biological functions maintained for therapeutic use.

Drug candidates by Disease Area

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As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM035	An anti-ENO1 antibody	Immune diseases, Various cancers	s.c.	Protein	US FDA IND cleared	GEM035 is a humanized antibody against unique ENO1 target. This therapeutic antibody is first-in-class to target inflammatory macrophage and demonstrates efficacy in animal models of MS, IPF, and IBD. It also showed efficacy in animal models of lung, pancreatic, and prostate cancer, most likely by targeting tumor associated macrophage (TAM). GEM035 may be developed for treatment of COVID-19 induced ARDS based on its capability to suppress macrophage related immune response. GEM035 has a worldwide patent protection. US IND of GEM035 is approved and active now for treating MS.
	GEM141	Esophageal implant (See note)	Pediatric esophageal atresia and other conditions that affect the esophagus	Implant (autologous)	Cell therapy	IND ready	Esophageal implant made by combining a novel cell therapy platform (see TGEM38) with a patient's own cells (hematopoietic stem and precursor cells). GEM141 leverages the body's inherent capacity to heal itself as it is a "living tube" that facilitates regeneration of esophageal tissue and triggers a positive host response resulting in a tissue-engineered neo-conduit that restores continuity of the esophagus. These implants have the potential to dramatically improve the quality of life for children and adults
	GEM170	Improved PCR	Diagnostic for detection of Paratuberculosis in animals and potentially Crohn's disease in humans	in vitro	Others	POC obtained in animals	New and improved PCR diagnostic test for fast and early detection of Mycobacterium avium subspecies paratuberculosis (MAP). This method shows better performance than current ELISA as well as on current PCR tests. Diagnostic test for early MAP detection in domestic livestocks, exotic ruminations and human patients. Discussions are available for Japanese companies and Chinese companies. * Successfully tested in feces, blood, milk, sperm and tissue samples
	GEM002	Kappa-opioid receptor agonist	Pain/Itching, Please refer to Note	Oral	Small molecule	Preclinical	Updated on January 11, 2019 Discontinued development for pain because of company strategy. Available for repositioning. Possible indications: Chronic pains (Back pain, Arthritis pain, Cancer pain, Post-herpetic neuralgia, Trigeminal neuralgia etc.), Pruritus, Irritable bowel syndrome
	GEM003	Selective glucocorticoid receptor agonist	RA/OA, Please refer to Note	Local	Small molecule	Preclinical	Updated on January 11, 2019 Expected to reduce unfavorable responses of glucocorticoids by selectivity of action (transrepression>transactivation) Discontinued development for RA/OA. Available for repositioning. Possible indications: Atopic dermatitis, Psoriasis, Asthma, COPD, Inflammatory bowel disease etc.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM049	Pan-NOX inhibitor	IBD, IPF, Neurodegenerative diseases	Oral	Small molecule	Preclinical	Highly potent NOX inhibitor : 20~50 times more potent than GKT-137831 Significant effects in DNBS-ulcerative colitis and LPS-induced acute inflammatory animal studies. Also showed positive results in IPF animal model. High oral bioavailability and clean off-targets profile
	GEM104	Interleukin-1 beta inhibition	Various types of colitis (IBD, Immune-related and chemotherapy-induced colitis)	Oral	Small molecule	Preclinical	-A known approved drug molecule developed for new therapeutic indications of treating and alleviating symptoms of various types of colitis. -Showed greater pharmacological effects than the reference drug, mesalazine, in reducing inflammatory colon swelling and intestinal ulceration, while restoring damaged intestinal membrane. -One of few products capable of repairing damaged intestine membrane caused by colitis. -Synergistic effect via different mechanism of actions, can provide greater medical benefits to patients suffering from IBD or various types of colitis caused by cancer treatment with chemo- or immuno-therapy.
	GEM112	Antibody against *H.pylori*-derived HSP60	Eradication of *H.pylori*	i.v.	Protein	Preclinical	Antibiotic-resistance *H.pylori* are getting serious and antibiotic therapy failure rate is over 20%. GEM112 is a highly specific antibody against H.Pylori-derived HSP60 which inhibits T cell proliferation and induces IL-10 and TGF-b1. GEM112 does not bind to human HSP60.
	GEM138	Biosimilar adalimumab	Same indications as adalimumab	i.v.	Antibody	Preclinical	Purified GEM138 is highly similar to adalimumab by SDS-PAGE. GEM138 and adalimumab show a similar response in a TNF-a ELISA assay. Plant-based technology (TGEM036) was applied for production of GEM138.
	GEM245	Recombinant protein based on complement inhibitor C4BP with anti-inflammatory and tolerogenic action	Autoimmune diseases including SLE, IBD and RA	s.c. injection	Protein	Preclinical (before GLP)	・Recombinant protein based on endogenous complement inhibitor C4BP exerts anti-inflammatory and tolerogenic action on dendritic cells. ・A novel biologic for immunomodulation, not immunosuppression. ・Reduces TLR-induced overproduction of proinflammatory cytokines (IL-12, TNF-alpha, IFN-gamma). ・Confirmed in vivo efficacy in SLE model, RA model, and DSS-induced colitis model. ・Global IP coverage (incl. compositions)
Gynecology	GEM096	Progesterone receptor agonist	Recurrent preterm birth	Oral	Small molecule	Phase 2 completed	Potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. An end of Phase 2 meeting was completed with the FDA.
	GEM098	GnRH receptor antagonist	Endometriosis and Uterine fibroids	Oral	Small molecule	Phase 1	In Phase 1b, GEM098 showed dose-dependent suppression of LH, FSH and E2. The suppressive effects on E2 lasted up to 24 hrs and were more excellent when compared with the published phase 1 data of Elagolix in healthy premenopausal women. No serious adverse events were seen and well tolerated up to 320 mg QD.

Drug candidates by Disease Area

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As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM072	Orally available somatostatin analogues	Metabolic syndromes, Acromegaly, Hyperprolactinemia etc.*	Oral	Protein	Preclinical	The technology and "know-how" to synthesize somatostatin analogues which will be more potent, more specific, stable and orally available have been established. A few analogues (at lead generation/optimization stage) with different combination of receptor selectivity and differential hormonal secretion inhibition properties are available. *: Congenital hyperinsulinism, insulinomas, glucagonomas
	GEM227	Octreotide with fatty acids bundles	carcinoid syndrome/ acromegaly	s.c.	Peptide conjugated fatty acid	Preclinical	GEM227 - can be produced in high quality and bind to HSA effectively. - Fatty acids bundle can effectively prolong serum half-life of octreotide and antiproliferative effect of GEM227 is similar to that of octreotide. - can effectively reduce serotonin level in xenograft mouse model.
Hematology	GEM001	TRPV-1 agonist	Rheumatoid arthritis, Please refer to Note	Oral	Small molecule	Phase 2a	Updated on January 11, 2019 Potently inhibits TNF-a production by oral administration. Discontinued development for RA. Available for repositioning. Possible indications: Neuropathic pain, Crohn's disease, Systemic lupus erythematosus, Cachexia, Acute infectious disease, Allergy, Pyrexia, Anemia, Diabetes, Diseases related TNF-α (Colitis, Psoriasis ets.)
	GEM179	Iron supply	Iron deficient anemia	i.v.	Nano particle	Phase 2	GEM179 is a PEGylated Iron oxide nano particle (IOP) with high macropharge uptake efficiency. GEM179 provide higher efficacy and better safety profilres (serum iron, ROS, hypersensitivity, iFGF23). Comprehensive patent portfolio exist globally.
	GEM097	Factor VIIa derivative	Bypassing therapy in hemophilia with inhibitors	i.v.	Protein	IND ready	GEM097 is rFVIIa fused to transferrin and has longer half-lives than rFVIIa in rats and monkeys. A cleavable linker between rFVIIa and transferrin of GEM097 allows minimal reduction of FVIIa activity due to fusion. Preclinical (GLP) toxicity studies did not show any toxic evidence in rats or monkeys.
	GEM061	Curcumin-releasing topical formulation (sustained release for about 24 hours)	Please refer to Note	Topical	Small molecule	Preclinical	Indication: Osteoarthritis, CV disease, chronic inflammatory disease, vascular disease (Sickle Cell) Note: Curcumin's utility: chronic pain, chronic inflammatory conditions such as osteoarthritis, vascular disease such as Sickle Cell and diabetes. This formulation addresses limitations of the poor oral bioavailability of curcumin. Preclinical efficacy demonstrated in an rodent arthritis model and a rodent diabetes model.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
Immunology /Inflammation	GEM-CVD02	Immune modulation (reduction of cytokine storm) with anti-viral medicine	COVID-19	Oral	Small molecule	Launch	COVID-19 progressing process is by first infecting from the virus and intriguing immune system modulated pro-inflammation, further proceeding to more serious inflammation, and later evolving to commencement of pro-fibrosis with infected pneumonia.TLR4 signaling pathway is closely associated with inflammation, immunity, and lung diseases. A TLR4 antagonist works well as an immune modulator for applications on pro-inflammatory diseases. GEM-CVD02 is a launched compound that has TLR4 antagonist activity and is expected the efficacy in combination of anti-viral medicine. GMP manufactured and FDA approved CTM capsules of this candidate are ready for clinical trial uses.
	GEM127	Antibiotic	Primary and secondary skin infection - Impetigo, folliculitis, furunculosis (human use)	Topical	Small molecule	Launched	· The first product on the market that combines the therapeutic benefits of a marketed antibiotic with an innovative transparent film-forming and bioadhesive delivery technology. · When applied to the lesion, generates a film that acts as a bioadhesive sustained release matrix, maintaining the optimum concentration of antibiotic in the skin for a period of 6-8 hours. · The bioadhesive film generated prevents the removal of the antibiotic from the lesion and acts as a protective dressing that prevents infection spreading.
	GEM207	A3 adenosine receptor (A3AR) agonist	Rheumatoid arthritis (RA), Psoriasis	Oral	Small molecule	Phase 3	・A3AR is highly expressed in inflammatory and cancer cells. Specific agonists of A3AR induce apoptosis of inflammatory cells but not normal cells. ・Very good safety profile as 1st line therapy. ・In the pahse-2b study (monotherapy vs placebo) for12 weeks in naive RA patients, the endpoint was achieved. ・In the pahse-2/3 study (monotherapy vs placebo) in moderate to severe psoriasis patients, it did not meet the primary endpoint at 12 weeks, but at 32 week the improvement of PASI score was significant vs at 16 week. ・A phase-3 study (vs MTX) in moderate to severe RA and a phase-3 study (vs apremilast) are ongoing.
	GEM036	Hematopoietic stem cell fucosylation	Prevention of infection & GvHD from hematopoietic stem cell transplantation	Infusion	Protein	Phase 3 ready with FDA SPA	In Phase 2 study: Statistically significant acceleration of immune system reconstitution (neutrophil/platelet recovery) Significantly reduced infection and GvHD Improved survival Positioned to be best-in-class No reports of adverse event specifically attributable to fucosylation

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM-CVD05	Immune-modulate and slow down the hyperactive active immune system from attacking lung cells (and other solid organs)	Prevention of Respiratory Failure by Treating Acute Respiratory Disease Syndrome Resulting from COVID-19 and other viral pandemics	Refer to Note*	Protein**	Phase 3 ready***	1. Treatment of blood/MSCs, Tregs, NK cells with GEM-CVD05 to improve their homing to patients' lungs, thereby enabling those cells to slow down the hyperactive immune attack on the lungs to help prevent deaths from respiratory failure. 2. Treatment of cells such as stem cells enabling them to home/engraft more effectively to the bone marrow and accelerating immune reconstitution with 'younger' immune cells for improved viral infected cell killing. *Infusion with blood, or MSCs, Tregs, NK cells to improve efficacy, safety and cost of care outcomes **Used to treat MSCs, Blood, Tregs, NK cells , Stem Cells to Prevent deaths from respiratory failure ***Phase 2 study for other indication has been completed.
	GEM037	Allosteric modulator of the CCR3 receptor	Asthma, Rhinitis	Oral	Small molecule	Phase 2a	In phase 2a: Highly significant effects on the methacholine provocative response Showed trends to improvement in EAR (Early Phase Allergic Response) Reduced induced sputum eosinophil percentage and increased percent blood eosinophil
	GEM243	Known and available under CDA	Mucositis Prevention and Treatment, Fibrotic Disease Treatment	Injectable or Oral	Small molecule	Phase 2	Small molecule drug for the prevention and treatment of chemotherapy and radiation therapy induced mucositis. Also shows activity intreating fibrotic diseases such as pulmonary fibrosis and NASH. GEM243 has successfully completed POC human clinical studies in head and neck cancer patients for chemotherapy-induced mucositis prevention with excellent results. GEM243 has shown to be extremely safe and highly effective in P1a, P1b, and P2a human clinical studies. Potentially useful in preventing and treating chemotherapy-induced pulmonary fibrosis and as a direct treatment for diseases such as Covid-19-induced pulmonary fibrosis, idiopathic pulmonary fibrosis, and NASH.
	GEM042	TLR4 antagonist	NAFLD, NASH, AIH, CLD and CD	Oral	Small molecule	Phase 2	NAFLD (nonalcoholic fatty liver disease): The phase 2 results demonstrated significant improvement on relevant diagnosis and biomarkers. NASH: has recently been approved by US FDA for Phase 2 trial (Feb in 2020) AIH (autoimmune hepatitis; orphan designation): The phase 2 (open label) results will be available soon. CLD(chronic liver disease by HCV infection): A strong trend of improvement of liver function and safety in Phase 2. CD (Crohn's disease): Good efficacy in three Phase 2 POC studies. The drug is safe and tolerable in these trials. Can be licensed to territories except Asia

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM083	Vasoconstriction and anti-inflammatory action	Hemorrhagic cystitis	Topical (Intravesical)	Small molecule	Phase 2	Pre-liposomal lyophilate containing tacrolimus. POC achieved in animal models of both chemo-cystitis and radiation cystitis. POC achieved in first-in-man experience treating severe recurrent hemorrhagic cystitis. Orphan drug designation granted.
	GEM244	Recombinant human CC10 protein - multiple mechanisms, replacement therapy	Chronic rhinosinusitis* Acute lung injuries**, including Severe acute respiratory infection, Smoke inhalation, ARDS, COPD exacerbation, and Chronic Lung Diseases**, including Bronchiolitis obliterans, Asthma, and COPD	Intranasal, Intravenous and Inhaled	Protein	*Phase 2 (Phase 1 completed) **Phase 1 (Preclinical completed)	GEM244 is a recombinant version of a naturally occurring secretoglobin protein and an unique, clinical-stage, first-in-class biologic for host defense, ARDS, shock, thrombosis, chronic lung diseases, and transplant. - Proof of pharmacology demonstrated in human infants and numerous animal models, for example anti-inflammatory, anti-fibrotic, and disease-modifying activity, allergy, asthma, COPD, lung repair, transplant, burns, shock, and pulmonary edema/pneumonia - Broad spectrum use in respiratory infection such as Influenza, COVID-19, RSV, possibly bacterial pneumonia - Genetic alleles correlate with deficiencies of the native secretoglobin to identify patients most likely to benefit from this therapy as a replacement of the native protein.
	GEM059	Recombinant Human Interleukin-1 Receptor Antagonist	Please refer to Note	IM	Protein	Phase 1	Indication: 1: Infection, as manifested by febrile neutropenia, in patients with malignancies receiving chemotherapy drugs. 2: Diarrhea in patients with malignancies receiving chemotherapy drugs. 3. Gout arthritis Note: The world's first multiorgan protection agent for tumor chemotherapy. Inhibits cell cycle progression of normal cells and renders them resistance to chemotherapy. No effects on tumor growth and their sensitivity to chemotherapy Phase 1 : No dose limiting toxicity, None of subjects presented grade 3 or above chemotherapy-induced neutropenia or diarrhea. Gout arthritis: Well tolerated and safe for patients who are restricted from NSAID, glucocorticoid, or colchicine.
	GEM073	Kinase inhibitor of TGFβ-mediated phospho-SMAD2 signal transduction	COPD, IPF, Lung cancer	Oral	Small molecule	Phase 1	This kinase is selectively expressed in resident macrophages and airways epithelia of the lung and upregulated in COPD and IPF patients. A highly selective inhibitor showed efficacy across at least 3 different animal models relevant to COPD, IPF and NSCLC. Phase 1 trial has completed with a clean safety and tolerability profile.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM155	FPR2-specific ligand	Atopic dermatitis/Psoriasis, Dry eye disease, IBD (Inflammatory bowel disease), Asthma, Rheumatoid arthritis	Topical, Eye drop, s.c.	Peptide	Phase 1	GEM155 is a small (7mer) lipidated peptide ligand for pro-resolving receptor FPR2 (N-formyl peptide receptor 2) involved in regulation of innate immune system and inhibition of ILC2 function (adaptive immune system). It also has anti-microbial effect for pathogenic bacteria through fusion with functional moiety. Efficacy is seen in animal models for the indications. CMC study is almost done. Toxicity study for topical usage and subcutaneous injection is going-on. Formulation for topical use is almost finished.
	GEM035	An anti-ENO1 antibody	Immune diseases, Various cancers	s.c.	Protein	US FDA IND cleared	GEM035 is a humanized antibody against unique ENO1 target. This therapeutic antibody is first-in-class to target inflammatory macrophage and demonstrates efficacy in animal models of MS, IPF, and IBD. It also showed efficacy in animal models of lung, pancreatic, and prostate cancer, most likely by targeting tumor associated macrophage (TAM). GEM035 may be developed for treatment of COVID-19 induced ARDS based on its capability to suppress macrophage related immune response. GEM035 has a worldwide patent protection. US IND of GEM035 is approved and active now for treating MS.
	GEM187	Mesenchymal stem cell	Rheumatoid Arthritis (RA), Inflammatory Bowel Disease (IBD), COVID-19	Implant (allogenic)	Cell	IND	GEM187 is a fresh (non-frozen) human allogenic umbilical cord tissue derived mesenchymal stem cells (hUC-MSC) product. - Proprietary manufacturing process with no risk of contamination. - “Youngest” adult MSC with robust proliferation capacity. - Highly scalable to achieve enough cells. - Superior biological functions: optimal cell viability and biological functions maintained for therapeutic use.
	GEM151	anti-GM-CSF monoclonal antibody	Rheumatoid arthritis & multiple new indications* (see note)	i.v.	Antibody	Preclinical (ready for IND-enabling studies)	GM-CSF is a key player in inflammation and autoimmunity. GEM151 is a fully human monoclonal antibody generated by single B cell cloning and has superior affinity (Kd: 7.3 X 10 -11 M) compared to competitors. Neutralizing activities were confirmed by four different functional assays. *cytokine release syndrome., GvHD, multiple sclerosis/neuroinflammation, Kawasaki disease
	GEM003	Selective glucocorticoid receptor agonist	RA/OA, Please refer to Note	Local	Small molecule	Preclinical	Updated on January 11, 2019 Expected to reduce unfavorable responses of glucocorticoids by selectivity of action (transrepression>transactivation) Discontinued development for RA/OA. Available for repositioning. Possible indications: Atopic dermatitis, Psoriasis, Asthma, COPD, Inflammatory bowel disease etc.

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM049	Pan-NOX inhibitor	IBD, IPF, Neurodegenerative diseases	Oral	Small molecule	Preclinical	Highly potent NOX inhibitor : 20~50 times more potent than GKT-137831 Significant effects in DNBS-ulcerative colitis and LPS-induced acute inflammatory animal studies. Also showed positive results in IPF animal model. High oral bioavailability and clean off-targets profile
	GEM051	Protective agents from heat stress	Heatstroke	Oral	Other	Preclinical	Suppression of vascular endothelial cell damage and production and release of inflammatory cytokines from blood cells due to heat stress. Ingredients derived from citrus fruit extract.
	GEM061	Curcumin-releasing topical formulation (sustained release for about 24 hours)	Please refer to Note	Topical	Small molecule	Preclinical	Indication: Osteoarthritis, CV disease, chronic inflammatory disease, vascular disease (Sickle Cell) Note: Curcumin's utility: chronic pain, chronic inflammatory conditions such as osteoarthritis, vascular disease such as Sickle Cell and diabetes. This formulation addresses limitations of the poor oral bioavailability of curcumin. Preclinical efficacy demonstrated in an rodent arthritis model and a rodent diabetes model.
	GEM069	Immuno-modulator (adjuvant)	Vaccine, Cancer immunotherapy etc.	Injection	Other	Preclinical	*E.coli* producing monophosphoryl Lipid A whose structure is similar to existing adjuvants such as MPL and GLA. Shows similar efficacy with MPL in vitro and in vivo. Lower cost production through simple fermentation and purification steps
	GEM138	Biosimilar adalimumab	Same indications as adalimumab	i.v.	Antibody	Preclinical	Purified GEM138 is highly similar to adalimumab by SDS-PAGE. GEM138 and adalimumab show a similar response in a TNF-a ELISA assay. Plant-based technology (TGEM036) was applied for production of GEM138.
	GEM143	CB1, CB2, 5-HT1a	Multiple Sclerosis (MS), Opioid addiction, Chemotherapy induced Peripheral Neuropathic Pain (CIPNP), and Epilepsy	Oral	Small molecule	Preclinical	GEM143 is a nanoencapsulation of the API in biodegradable polymer nanospheres for improved oral bioavailability. MS: The API has multiple actions on key molecular neuroinflammation and neurodegeneration targets, with highly effective in vitro and in vivo bioactivities. Opioid addiction: The API is not an opioid and has been shown to alleviate cue-induced opioid addiction behaviors and allosterically modulate the μ and δ-opioid receptors. CIPNP: Nanoencapsulation is being used to protect the API during the stomach passage. Epilepsy: The API is an effective anti-convulsant with a specificity more comparable to drugs clinically effective in major seizures.

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM146	VD Receptor	Prostate cancer, Autoimmune diseases	i.v.	Small molecule	Preclinical	GEM146 is a nanosomal formulation of a nontoxic Vitamin D3 analog. In vivo studies have shown strong anticancer effects of GEM146 against Hormone Refractory Prostate Cancer xenografts in nude mice at doses approximately 6.5 times less than the parent hormone, without significant toxicity.
	GEM209	A3 adenosine receptor (A3AR) allosteric modulator	Erectile dysfunction	Oral	Small molecule	Preclinical	・Specific agonists of A3AR induce modulation of key signaling proteins, such as PI3K, GSK-3β, PKA, PKB/Akt, IKK, and NF-κB, and show anti-inflammatory effects. ・Very good safety profile. ・GEM209 increased eNOS and VEGF in the cavernosal endothelial cells. ・A single dose showed a full recovery in function of in an erectile dysfunction rat model.
	GEM213	Anti-CSF-1R antibody	Cancer, PVNS (pigmented villonodular synovitis)	i.v.	Antibody	Preclinical	GEM213 is an antibody with high affinity and neutralizing ability. - GEM213 can potently inhibit Colony Stimulating Factor Receptor 1 (CSF-1R) in cellular contexts and has the potential to induce a therapeutic effect on macrophages. - GEM213 has unique CDR sequences and epitopes. - GEM213 is a promising new agent with potential to combine with immune checkpoint inhibitors to relief macrophage-dependent immune suppression and would yield clinical benefit.
	GEM239	Activation of Treg and downregulating pro-inflammatory cytokines	Psoriasis, Please refer to Note	Oral	Small molecule	Human POC completed	Microbiomes are important for regulating human immune systems.GEM239 is a small molecule known as a gut microbial metabolite. It downregulates pro-inflammatory cytokines, and promotes differentiation of anti-inflammatory Treg cells. Human POC study in a small number of psoriasis patients has been done and significant treatment effects have been seen. FDA IND approved. Clinical trial starting in 30 patients. Potential indications may include psoriatic arthritis, rheumatoid arthritis, ankylosing spondulitis, Crohn's and colitis. Formulation-science has been applied.
	GEM245	Recombinant protein based on complement inhibitor C4BP with anti-inflammatory and tolerogenic action	Autoimmune diseases including SLE, IBD and RA	s.c. injection	Protein	Preclinical (before GLP)	・Recombinant protein based on endogenous complement inhibitor C4BP exerts anti-inflammatory and tolerogenic action on dendritic cells. ・A novel biologic for immunomodulation, not immunosuppression. ・Reduces TLR-induced overproduction of proinflammatory cytokines (IL-12, TNF-alpha, IFN-gamma). ・Confirmed in vivo efficacy in SLE model, RA model, and DSS-induced colitis model. ・Global IP coverage (incl. compositions)

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM258	A novel Peptide Targeting a STAP-2-TCR (T cell receptor)	Autoimmune disease	i.v.	Peptide	Preclinical	STAP-2 belongs to a family of STAP adaptor proteins and plays a crucial role in a variety of cellular signal transduction pathways, in particular, regulates both the innate and adaptive immune systems. STAP-2 is involved in the initiation of TCR signaling by forming a trimeric complex with LCK and CD3ζ. Peptidic GEM258 binding ITAM motif in STAP-2 inhibits the T cell proliferation and T lymphoma proliferation in vitro and improved the EAE (experimental autoimmune encephalomyelitis) pathological score in vivo.
	GEM262	Anti-Inflammatory Drug derived from Resolvin E2	SLE, IBD,RA,Psoriasis, Pain	p.o.	Small molecule	Preclinical	The anti-inflammatory effects of Resolvin E2 are even more potent than clinically effective steroidal and nonsteroidal anti-inflammatory drugs. GEM262 is a new stable compound as an equivalent of Resolvin E2 and promotes the resolution of inflammation by inhibiting neutrophil infiltration and promotion phagocytosis of macrophages in remarkably low doses.
Infection	GEM127	Antibiotic	Primary and secondary skin infection - Impetigo, folliculitis, furunculosis (human use)	Topical	Small molecule	Launched	· The first product on the market that combines the therapeutic benefits of a marketed antibiotic with an innovative transparent film-forming and bioadhesive delivery technology. · When applied to the lesion, generates a film that acts as a bioadhesive sustained release matrix, maintaining the optimum concentration of antibiotic in the skin for a period of 6-8 hours. · The bioadhesive film generated prevents the removal of the antibiotic from the lesion and acts as a protective dressing that prevents infection spreading.
	GEM130	Antiviral	Infections caused by herpes simplex virus in face and lip	Topical	Small molecule	Launched	· First cold sore product on the market that combines the therapeutic benefits of an antiviral with an innovative transparent bioadhesive film. · When applied to the lesion, generates a transparent film that acts as a bioadhesive sustained matrix release that improves product bioavailability while promotes itching reduction and wound healing. · Indicated for the topical treatment of symptoms (tingling, burning, discomfort) of recurrent herpes labialis caused by herpes simplex virus (VHS).
	GEM-CVD02	Immune modulation (reduction of cytokine storm) with anti-viral medicine	COVID-19	Oral	Small molecule	Launch	COVID-19 progressing process is by first infecting from the virus and intriguing immune system modulated pro-inflammation, further proceeding to more serious inflammation, and later evolving to commencement of pro-fibrosis with infected pneumonia.TLR4 signaling pathway is closely associated with inflammation, immunity, and lung diseases. A TLR4 antagonist works well as an immune modulator for applications on pro-inflammatory diseases. GEM-CVD02 is a launched compound that has TLR4 antagonist activity and is expected the efficacy in combination of anti-viral medicine. GMP manufactured and FDA approved CTM capsules of this candidate are ready for clinical trial uses.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM168	Heat-killed mycobacterium vaccae	Tuberculosis (TB)	Oral	Vaccine	Phase 3	First-in-class tuberculosis immunotherapy to be used as an oral adjunct to standard TB drugs. In a 1-month phase 2 trial, the mycobacterial clearance in sputum smears was observed in 72% and 19% of patients on GEM168 and placebo, respectively.
	GEM-CVD05	Immune-modulate and slow down the hyperactive active immune system from attacking lung cells (and other solid organs)	Prevention of Respiratory Failure by Treating Acute Respiratory Disease Syndrome Resulting from COVID-19 and other viral pandemics	Refer to Note*	Protein**	Phase 3 ready***	1. Treatment of blood/MSCs, Tregs, NK cells with GEM-CVD05 to improve their homing to patients' lungs, thereby enabling those cells to slow down the hyperactive immune attack on the lungs to help prevent deaths from respiratory failure. 2. Treatment of cells such as stem cells enabling them to home/engraft more effectively to the bone marrow and accelerating immune reconstitution with 'younger' immune cells for improved viral infected cell killing. *Infusion with blood, or MSCs, Tregs, NK cells to improve efficacy, safety and cost of care outcomes **Used to treat MSCs, Blood, Tregs, NK cells , Stem Cells to Prevent deaths from respiratory failure ***Phase 2 study for other indication has been completed.
	GEM196	Potassium-Competitive Acid Blocker (P-CAB)	Peptic ulcer	Oral	Small molecule	Phase 3	Phase 3 is ongoing. P-CABs are the best treatment with better and faster efficacy for gastric acid-related gastrointestinal diseases such as gastric and duodenal ulcer, GERD, NERD, ZES and etc. GEM196 is a potentially best-in-class P-CAB - Faster clinical benefit in phase 2 study compared with Lansoprazole for duodenal ulcer treatment. - Rapid and high absorption, oral bioavailability in clinical study. - Lower toxicity and better PK, PD than TAK-438. - Acid stability- exempt acid protection - Longer lasting-higher concentration on target site - Less individual differences- isoenzyme CYP2C19 metabolism tiny dependence.
	GEM001	TRPV-1 agonist	Rheumatoid arthritis, Please refer to Note	Oral	Small molecule	Phase 2a	Updated on January 11, 2019 Potently inhibits TNF-a production by oral administration. Discontinued development for RA. Available for repositioning. Possible indications: Neuropathic pain, Crohn's disease, Systemic lupus erythematosus, Cachexia, Acute infectious disease, Allergy, Pyrexia, Anemia, Diabetes, Diseases related TNF-α (Colitis, Psoriasis ets.)
	GEM144	PKC modulator plus HDAC inhibitor	HIV Latency	i.v., Oral	Small molecule	Phase 2a	GEM144 is a nanoencapsulation of PKC modulators plus HDAC inhibitor in targeted, pegylated phospholipid nanosomes for improved therapeutic index. Activates HIV from latent reservoirs so that HIV can be eradicated from the body by antiviral therapy and/or immune system.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM042	TLR4 antagonist	NAFLD, NASH, AIH, CLD and CD	Oral	Small molecule	Phase 2	NAFLD (nonalcoholic fatty liver disease): The phase 2 results demonstrated significant improvement on relevant diagnosis and biomarkers. NASH: has recently been approved by US FDA for Phase 2 trial (Feb in 2020) AIH (autoimmune hepatitis; orphan designation): The phase 2 (open label) results will be available soon. CLD(chronic liver disease by HCV infection): A strong trend of improvement of liver function and safety in Phase 2. CD (Crohn's disease): Good efficacy in three Phase 2 POC studies. The drug is safe and tolerable in these trials. Can be licensed to territories except Asia
	GEM129	Immuno-modulator	Anogenital warts, Actinic keratosis, Basal cell carcinoma	Topical	Small molecule	Phase 2	· The first product on the market that combines the therapeutic benefits of a marketed immunomodulator with an innovative transparent bioadhesive film. · When applied to the lesion, generates a transparent bioadhesive film, which acts as a reservoir or matrix release and reduces the local reactions and increases the permanence of the product in the action site. · The results of non-clinical studies demonstrate that GEM129 has a better safety profile with an equivalent efficacy than its reference product. Clinical studies on-going.
	GEM244	Recombinant human CC10 protein - multiple mechanisms, replacement therapy	Chronic rhinosinusitis* Acute lung injuries**, including Severe acute respiratory infection, Smoke inhalation, ARDS, COPD exacerbation, and Chronic Lung Diseases**, including Bronchiolitis obliterans, Asthma, and COPD	Intranasal, Intravenous and Inhaled	Protein	*Phase 2 (Phase 1 completed) **Phase 1 (Preclinical completed)	GEM244 is a recombinant version of a naturally occurring secretoglobin protein and an unique, clinical-stage, first-in-class biologic for host defense, ARDS, shock, thrombosis, chronic lung diseases, and transplant. - Proof of pharmacology demonstrated in human infants and numerous animal models, for example anti-inflammatory, anti-fibrotic, and disease-modifying activity, allergy, asthma, COPD, lung repair, transplant, burns, shock, and pulmonary edema/pneumonia - Broad spectrum use in respiratory infection such as Influenza, COVID-19, RSV, possibly bacterial pneumonia - Genetic alleles correlate with deficiencies of the native secretoglobin to identify patients most likely to benefit from this therapy as a replacement of the native protein.

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	GEM-CVD03	Fast response oral vaccine	COVID-19	Oral	Vaccine	Phase 1/2	First-in-class COVID-19 immunotherapy to be used as an oral vaccine. This company has a track record to manufacture oral vaccine against highly pathogenic avian flu virus H5N1 on one week time. Oral vaccine will be easier to distribute to a large number of potentially virus-exposed people within very short period of time. The company is looking for partner who make the company accessing the virus and finance to manufacture the first batch within one week.
	GEM-CVD04	- Antiviral - Immunomodulatory - Anticoagulant - cytokine release control	Pre-Exposure and Post Exposure Prophylaxis for COVID-19	Oromucosal (dissolves in the mouth)	Small molecules	Phase 1*	- Multi-targeted action - Systemic absorption and topical exposure to upper respiratory tract. colonized by COVID-19 virus. - *Entering Phase 2 for other indication (USA). - Available for a large clinical trial (GMP). - Excellent safety profile - Worldwide patents
	GEM-CVD08	An anti-SARS-COV-2 S1 RBD antibody	COVID-19	i.v.	Protein	Phase 1	> 10 fold higher binding affinity and >50 fold more potent blocking potency than soluble hACE2-Fc. Neutralize authentic SARS-COV-2 virus infection of Vero E2 cells at IC50 = 0.012 - 0.062 µg/ml. Showed binding and blocking activity against South Africa and UK mutants. Engineered Fc to reduce potential ADE risk. Obtained CHO-K1 CMC clone with high expression titer. Showed potent prophylactic and desired therapeutic efficacy in rhesus monkey disease model.
	GEM059	Recombinant Human Interleukin-1 Receptor Antagonist	Please refer to Note	IM	Protein	Phase 1	Indication: 1: Infection, as manifested by febrile neutropenia, in patients with malignancies receiving chemotherapy drugs. 2: Diarrhea in patients with malignancies receiving chemotherapy drugs. 3. Gout arthritis Note: The world's first multiorgan protection agent for tumor chemotherapy. Inhibits cell cycle progression of normal cells and renders them resistance to chemotherapy. No effects on tumor growth and their sensitivity to chemotherapy Phase 1 : No dose limiting toxicity, None of subjects presented grade 3 or above chemotherapy-induced neutropenia or diarrhea. Gout arthritis: Well tolerated and safe for patients who are restricted from NSAID, glucocorticoid, or colchicine.

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	GEM-CVD01	SARS-CoV-2 spike protein expression from RNA followed by antibody response	COVID-19	Intramuscular	RNA Vaccine	Phase 1	This program is a rapid COVID-19 vaccine development. This vaccine is developed on the basis of established technologies of RNA delivery and nanostructured lipid carrier formulation. GEM-CVD01 rapidly induces robust immune responses.
	GEM-CVD06	A potent DNA-immunotherapy against SARS-CoV-2	COVID-19	Intravenous Injection	In vivo CAR-T	Preclinical	DNA vector with Anti-CoV-2 Receptors inserted into our original platform (TGEM052) and delivered through liposomes into lymph nodes. The plasmid moves into the nucleus of normal T-cells and converted to CAR. Anti-CoV-2 CAR T-cells attack the virus and diseased cells and destroy them.
	GEM033	Inhibitors of bacterial resistance mechanisms	Gram-negative MDR bacterial infections, Lung infections in cystic fibrosis (CF) patients	Intravenous, Aerosol, Topical	Small molecule	Preclinical	Restore effectiveness of shelved antibiotics. Lower the effective dose of antibiotics. Mitigate antibiotic resistance. Disrupt biofilm-based infections. Over 1,000 compounds with lead compounds for each indication identified.
	GEM039	Antifungal	Onychomycosis	Topical	Small molecule	Preclinical	Novel and unique topical formulation of Terbenafine with exceptional permeation (40 fold) across the human nail. Potential for OTC or RX introduction: minimal development timeline
	GEM112	Antibody against *H.pylori*-derived HSP60	Eradication of *H.pylori*	i.v.	Protein	Preclinical	Antibiotic-resistance *H.pylori* are getting serious and antibiotic therapy failure rate is over 20%. GEM112 is a highly specific antibody against H.Pylori-derived HSP60 which inhibits T cell proliferation and induces IL-10 and TGF-b1. GEM112 does not bind to human HSP60.
	GEM120	Inhibition of membrane binding of Pr55Gag	HIV	i.v.	Small molecule	Preclinical	· Inhibited the membrane localization of Pr55Gag and stopped budding of HIV virus. · Captures HIV in immune cells and induces apoptosis of the HIV-infected immune cells.
	GEM139	*Staphylococcus aureus* vaccine	*Staphylococcus aureus* infection	s.c.	Vaccine	Preclinical	The vaccine comprising antigens and toxin is being developed. The candidate antigens to block the immune-evasion pathway by MSCRAMMs and toxin of *S. aureus* have already been defined.
	GEM148	CCR5 inhibition	HIV	i.v.	Nucleic acid	Preclinical	GEM148 is a nanoencapsulation of proprietary, synthetic CCR5-siRNA targeted to knock-down and eliminate HIV-1 in chronic HIV patients as well as prevent HIV-1 infection in naïve patients and re-infection in acutely-infected patients.

Drug candidates by Disease Area

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	GEM200	Physically damage bacterial membranes	Multidrug-resistant bacteria	i.v.	Peptide	Preclinical	A bioengineered peptide that is effective against Gram(-) bacteria and works regardless of any underlying resistance the bacteria may have against other antibiotic drugs. GEM200 is highly efficient against Multi Drug Resistant Acinetobacter baumannii in hospital acquired infections and its unique MoA lowers the probability for development of future resistance or tolerance. GEM200 is Effective where the Standard of Care drugs fail. Advantages: - High efficacy in systemic IV administration - Rapid bactericidal MOA that avoids resistance - Targets bacteria only – Non-toxic to human cells - Stable peptides with T1/2=~8 hours in human plasma
	GEM201	mRNA Vaccine Platform technology. Production of S-Protein with Immune-modulators in one construct.	Coronavirus (COVID-19); Broader Vaccine Platform	i.v.	Drug Delivery, Cell therapy	Preclinical	GEM201 utilizes TGEM055 technology loaded with antigenetic proteins as a mRNA Vaccine Platform - Produce functional antigenetic proteins in Lymphatic organs - Localized antigen induction at high intracellular amounts where antigen presenting cells aggregate. Co-delivery of potent Immune-modulators (GM-CSF, IL-12, etc.) simultaneously - GEM201 is a vaccine platform - GEM201 is critical for vaccination of elderly and immune suppressed population
	GEM214	Anti-K. pneumoniae (KP) Antibodies	Multiple Drug Resistant (MDR) Klebsiella pneumoniae (KP) infection	i.v.	Antibody	Preclinical	GEM214 is an anti-MDR therapeutic antibody against Klebsiella pneumoniae Infection. -A fully human mAb, has longer half-life and low immunogenicity. -Antibody Antibiotics Conjugate (AAC) of GEM214 shows dose dependent intracellularly bactericidal potency.
	GEM234	Crosstalk of TGF-β signal and Wnt/β-catenin signal	Liver fibrosis, Nonalcoholic steatohepatitis, Kidney fibrosis, Renal fibrosis, Liver cancer, COVID-19	Injection	Small molecule	Preclinical	GEM234 is a novel small molecular which has suppressive effects on both hepatic stellate cell activation and kidney and liver fibrosis by suppressing TGF-β/Smad pathway via inhibition effect of Wnt/β-catenin pathway. GEM234 shows a higher suppressive effect on liver cancer stem cells than 5-FU. Wnt/β catenin inhibitors can block the infection of SARS-Cov-2, and GEM234 has potential to prevent occurrence of ARDS and cardiovascular damage in COVID-19.

Drug candidates by Disease Area

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	GEM246	Anti-SARS-Cov-2 IgY antibody	COVID-19	Intra-nasal or inhalation	Antibody	Preclinical	・IgY antibody extracted from egg yolk of hens immunized with SARS-Cov-2 virus. ・The highest concentration of antibodies in the animal kingdom is found in a single egg yolk ・Faster and lower cost in manufacturing vs monoclonal antibody ・Could be used for both therapeutic and prophylactic purposes (passive immunization) ・Looking for partners in Japan and South Korea.
	GEM253	Influenza Virus-Neutralizing antibody	Influenza	i.v.	Antibody	Preclinical	Neutralizing activity against Influenza virus, human H1N1, H2N2, H3N2, H5N1 and avian H3N8. Passive immunization with the pan-neutralizing antibody enables to effectively prevent or treat influenza even in the event of an antigenic shift, as well as an antigenic drift.
	GEM263	Viral RNA replication inhibitor	Flaviviruses and Coronaviruses, including SARS-CoV-2	p.o.	Small molecule	Preclinical	GEM263 possessed both potent anti-flavivirus and anti-coronavirus activities at submicromolar levels without significant cytotoxicity. GEM263 inhibited viral RNA replication and specifically inhibited replication at the late stages of the SARS-CoV-2 infection process. GEM263 5'-triphosphate inhibited RNA extension catalyzed by the viral RNA-dependent RNA-polymerase, too. GEM263 has the potential of serving as a lead compound for the development of a broad spectrum of antiviral agents, including SARS-CoV-2.
	GEM212	Antivirulent approach targeting antimicrobial resistance of *Staphylococcus aureus* infections	*S. aureus* and MRSA	Oral	Small molecule	Near completion of IND stage	An antivirulent, non-bactericidal small molecule drug candidate for *S. aureus* infections, including MRSA, in a first-in-class oral form. Potentially reduces the risk of *S. aureus* resistance. A new mechanism to enhance the killing action of neutrophils. Phase II clinical trials are planned across multiple indications; bacteremia, pneumonia, endocarditis, bone and joint infections.
	GEM-CVD07	CK2 inhibitor	COVID-19	Oral	Small molecule	IND#	・A promising therapeutic compound due to its dual impact on COVID-19 *Block stress granule disaggregation required for active viral replication *Reduce cytokine storm ・GEMCVD07 demonstrates potent anti-SARS-CoV-2 activity. ・In process of filing for emergency IND (eIND) to U.S. FDA to test ten patients. #Phase 2 clinical trial is ongoing for other indication.

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	GEM187	Mesenchymal stem cell	Rheumatoid Arthritis (RA), Inflammatory Bowel Disease (IBD), COVID-19	Implant (allogenic)	Cell	IND	GEM187 is a fresh (non-frozen) human allogenic umbilical cord tissue derived mesenchymal stem cells (hUC-MSC) product. - Proprietary manufacturing process with no risk of contamination. - “Youngest” adult MSC with robust proliferation capacity. - Highly scalable to achieve enough cells. - Superior biological functions: optimal cell viability and biological functions maintained for therapeutic use.
	GEM163	Reduction of virus-replication and reduction of inflammation	Virus diseases (incl. coronaviruses)**	Oral	Oligo-saccharides	NDIN** ready	A novel, intestinally absorbable derivative (pat. pend.) of GRAS αCD (α-cyclodextrin) to reduce virus entry (endocytosis) and replication/assembly of viruses (availability of lyso-phospholipids). βCDs have been effective in vitro against many virus infections, incl. coronaviruses, and topically against influenza and HSV2. αCDs avoid the ototoxicity of βCDs and were more effective (tested in HIV-1 cells). **New dietary ingredient notification as a nutritional supplement/FSMP
	GEM170	Improved PCR	Diagnostic for detection of Paratuberculosis in animals and potentially Crohn's disease in humans	in vitro	Others	POC obtained in animals	New and improved PCR diagnostic test for fast and early detection of Mycobacterium avium subspecies paratuberculosis (MAP). This method shows better performance than current ELISA as well as on current PCR tests. Diagnostic test for early MAP detection in domestic livestocks, exotic ruminations and human patients. Discussions are available for Japanese companies and Chinese companies. * Successfully tested in feces, blood, milk, sperm and tissue samples
	GEM211	Antiviral	Influenza A	Oral	Small molecule	Lead optimization stage	An antiviral with a more upstream target than Tamiflu, shown to be more effective *in vivo* . A small molecule, nucleozin, which targets viral nucleoprotein (NP), triggering the aggregation of NP and inhibiting its nuclear accumulation. This impedes viral replication *in vivo* .
Liver disease	GEM208	A3 adenosine receptor (A3AR) agonist	Liver cancer* NAFLD**	Oral	Small molecule	Phase 3 in preparation* Phase 2 completed**	・A3AR is highly expressed in inflammatory and cancer cells. Specific agonists of A3AR induce apoptosis of cancer cells but not normal cells. ・Very good safety profile. ・An orphan drug status for hepatocellular carcinoma (HCC). ・In phase-2 study in HCC patients, it did not meet the primary endpoint (OS) but subgroup analysis of Child Pugh B patients showed a positive signal of efficacy for OS. ・In phase-2 study (vs placebo) in NAFLD/NASH, it met primary endpoint (liver enzyme) and reduced liver fat, fibrosis and steatosis.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM042	TLR4 antagonist	NAFLD, NASH, AIH, CLD and CD	Oral	Small molecule	Phase 2	NAFLD (nonalcoholic fatty liver disease): The phase 2 results demonstrated significant improvement on relevant diagnosis and biomarkers. NASH: has recently been approved by US FDA for Phase 2 trial (Feb in 2020) AIH (autoimmune hepatitis; orphan designation): The phase 2 (open label) results will be available soon. CLD(chronic liver disease by HCV infection): A strong trend of improvement of liver function and safety in Phase 2. CD (Crohn's disease): Good efficacy in three Phase 2 POC studies. The drug is safe and tolerable in these trials. Can be licensed to territories except Asia
	GEM094	Androgen receptor agonist	NASH, Pre-Cirrhosis	Oral	Small molecule	Phase 2 ongoing	An oral prodrug of bioidentical testosterone that is being developed as a treatment of non-alcoholic steatohepatitis (NASH) and is being studied in the LifT Phase 2 clinical study in biopsy confirmed NASH subjects.
	GEM095	Androgen receptor agonist	NASH, Cirrhosis	Oral	Small molecule	Phase 1	An oral prodrug of bioidentical testosterone that is being developed as a treatment of cirrhotic non-alcoholic steatohepatitis (NASH).
	GEM185	GLP-1/GIP dual agonist	Obesity, diabetes, NAFLD/NASH	s.c.	Peptide	Phase 1	1) GEM185 demonstrated the improvement of hyperglycemia in a clinical trial - Dual agonist for GLP-1R/GIPR is a validated target in treating diabetes and obesity - GEM185 is a potent dual agonist for GLP-1R/GIPR - GEM185 decreased glucose levels in patients with diabetes - Safe and well tolerated - Once daily dosing potential via injection - Weekly formulation is ongoing 2) R&D status - Phase 1 on-going - No longer available for licensing to Asia/Pacific excluding Japan.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM184	GPR40 full agonist	Obesity, diabetes, NAFLD/NASH	Oral	Small molecule	Phase 2 ready	GEM184 demonstrated breakthrough drug profiles for the treatment of diabetes in a clinical trial. - Clinically validated small molecule activating pleiotropic biological effects of islet and gut hormones - Safe and well tolerated - Once daily oral dosing potential - Eliminated primarily via non-renal route - Stimulation of islet (insulin, glucagon) and gut (GLP-1, GIP, and PYY) hormone secretions - Remarkable effect in decreasing fasting hyperglycemia and improving glycemic control during a glucose tolerance test in patients with diabetes, without inducing hypoglycemia, making GEM184 an attractive drug candidate for the treatment of diabetes
	GEM124	Improves endothelial cell function and cellular fluidity. Antiatherosclerotic, anti-inflammatory, anti-fibrotic, fat-targeting composition	1) Atherosclerosis (#) 2) Treatment of NASH (Stage F2-F3) Fibrosis with no worsening of fibrosis.	Oral	Small molecule	Preclinical	1) Developed to target vulnerable, high risk plaques while also reducing LDL cholesterol, increasing HDL cholesterol and reducing Triglycerides. (#) Future indications: primary prevention of Heart Attack, Stroke and Death and Secondary Prevention of Myocardial Infarction in Europe. US Patent to treat Atherosclerosis is valid until 2035. 2) Concurrently being developed to treat liver inflammation, fibrosis and fat accumulation while also reducing LDL cholesterol and Triglycerides. *May be used in combination with other drugs, such as Intercept's Ocaliva that increases Triglycerides or Gilead's NASH candidate that increases LDL cholesterol.
	GEM203	FXR agonist and 5-HTR2A antagonist	NAFLD, Type 2 diabetes, obesity, dyslipidemia and hypertension	Oral	Small molecule	Preclinical	First in class single molecule having both FXR agonistic and 5-HTR2A antagonistic actions. In DIO mice, GEM203 reduced hyperglycemia, hyperinsulinemia, insulin resistance and liver lipid contents to similar or greater extent vs metformin. GEM203 reduced the body excess weight while metformin did not. In NASH model mice, GEM203 reduced liver excess weight, TG and TC contents, plasma ALT and AST, inflammation and collagen gene expression in the liver. Strong IP portfolio with long expiry dates granted in major markets.
	GEM228	GLP-1 with fatty acids bundles	Type2 Diabetes, obesity; NASH	s.c.	Peptide conjugated fatty acid	Preclinical	GEM228 -can be produced in high quality. -can lower blood glucose better than semaglutide and effectively control blood glucose level at 10 nmol/kg - can effectively reduce body weight and reduce liver fat

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	GEM171	ARNT regulation	Fibrosis in kidney, heart and liver	Oral / or gene therapy	Small molecule or morpho-linos	Discovery – Preclinical	No effective therapy for fibrosis is available yet. ARNT homodimerizartion attenuates fibrosis progression and induces regenerative cellular responses. Several mechanisms of action and potential drugs were identified, which show inhibition of ARNT degradation or activation of ARNT expression. PCT patent application filed. Discussions are available for Japanese companies and Chinese companies.
Metabolic disorder	GEM161	Restoration of autophagy and reduction of inflammation	Cardiovascular and Metabolic disorder	Oral	Oligo-saccharides	Phase 2b/3 ready	A novel derivative (pat. pend.) of hydroxypropyl-α-cyclodextrin (HPαCD) that down-regulates the PI-system by controlling serum phospholipids and, thereby, reduces endocytosis. βCDs have been shown to be effective in vivo against atherosclerosis (AS), NAFLD, but can cause permanent hearing loss (not applicable to αCDs). Oral αCD is clinically effective against metabolic syndrome, but has low and variable bioavailability. 505(b)(2) is applicable.
	GEM058	Increase cellular ATP and promote wound healing	Diabetes foot ulcer	Topical	Small molecule	Phase 2 Completed	Reducing inflammation of endothelial cells of blood vessels. Increasing cellular ATP and speeding up the healing of wounds by promoting the migration of epithelia cells in the skin of wounds. The arrangement of actin which is essential for cell migration is ATP dependent. Applicable to all kind of wound and low cost treatment Phase 2: The estimated complete closure rate is around 60% (vs placebo 30%)
	GEM233	Inhibition of pro-cytokines, enhancement of growth factor PDGF	Diabetic foot and leg ulcers	Topical	Botanical	Phase 2 Completed	Small molecules from soybean extract. MOA facilitates multiple phases at molecular levels of wound healing processes. Effective in STZ induced diabetic wound model and cell migration quality control. In Phase 2 study, ulcer complete closure rate up to 12 weeks is 32.7% in GEM233 group vs 15.4% in placebo group. Subjects in the GEM233 group had an average of 73±2.9 days to achieve ≥ 90% reduction in target ulcer size.
	GEM094	Androgen receptor agonist	NASH, Pre-Cirrhosis	Oral	Small molecule	Phase 2 ongoing	An oral prodrug of bioidentical testosterone that is being developed as a treatment of non-alcoholic steatohepatitis (NASH) and is being studied in the LifT Phase 2 clinical study in biopsy confirmed NASH subjects.

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	GEM243	Known and available under CDA	Mucositis Prevention and Treatment, Fibrotic Disease Treatment	Injectable or Oral	Small molecule	Phase 2	Small molecule drug for the prevention and treatment of chemotherapy and radiation therapy induced mucositis. Also shows activity intreating fibrotic diseases such as pulmonary fibrosis and NASH. GEM243 has successfully completed POC human clinical studies in head and neck cancer patients for chemotherapy-induced mucositis prevention with excellent results. GEM243 has shown to be extremely safe and highly effective in P1a, P1b, and P2a human clinical studies. Potentially useful in preventing and treating chemotherapy-induced pulmonary fibrosis and as a direct treatment for diseases such as Covid-19-induced pulmonary fibrosis, idiopathic pulmonary fibrosis, and NASH.
	GEM265	Enteropeptidase inhibitor	Kidney diseases, Diabetes	Oral	Small molecule	Phase 2	1) GEM265 is an orally bioactive enteropeptidase inhibitor with a first-in-class potential. 2) GEM265 showed therapeutic efficacy in pre-clinical disease models with kidney diseases and diabetes. 3) Phase 1 and Phase 2a studies were completed. - Good safety and tolerability were confirmed (up to 1500 mg/day was safe and well tolerated for 12 weeks). - GEM265-induced biomarker change (plasma amino acid changes) was confirmed. - GEM265 treatment for 12 weeks resulted in a significant reduction on urine albumin-to-creatinine ratio (UACR) from baseline in patients with diabetic kidney disease (DKD) treated with anti-hyperglycemic agents as well as renin-angiotensin system inhibitors. GEM265 also decreased HbA1c levels in DKD patients.
	GEM184	GPR40 full agonist	Obesity, diabetes, NAFLD/NASH	Oral	Small molecule	Phase 2 ready	GEM184 demonstrated breakthrough drug profiles for the treatment of diabetes in a clinical trial. - Clinically validated small molecule activating pleiotropic biological effects of islet and gut hormones - Safe and well tolerated - Once daily oral dosing potential - Eliminated primarily via non-renal route - Stimulation of islet (insulin, glucagon) and gut (GLP-1, GIP, and PYY) hormone secretions - Remarkable effect in decreasing fasting hyperglycemia and improving glycemic control during a glucose tolerance test in patients with diabetes, without inducing hypoglycemia, making GEM184 an attractive drug candidate for the treatment of diabetes

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM190	Lipase inhibition, α-amylase inhibition, aldehyde dehydrogenase (ALDH) activation and anti-oxidant capacity increase	Overweight and obesity Alcohol and tobacco smoke toxicity	Oral	Natural product	Clinical	GEM190 is a combination of two purified plant extracts in a form of oral liquid food supplement developed for appetite and weight control. Also, it reduces alcohol and tobacco smoke toxicity by activation of aldehyde dehydrogenase (ALDH) and increasing anti-oxidant capacity. In overweight and obese patients, GEM190 showed significant suppression of appetite and reduction of body weight and body fat as well as it had a beneficial effect on fluid distribution during weight loss, as observed in 12-week treatment. Increased ALDH activity in PBMC was observed already after 24 hours after initiation of GEM190 administration. GEM190 may provide a salvage solution in populations known to be particularly susceptible to a build-up of excess acetaldehyde, such as having a ALDH2*2 genetic mutation. GEM190 claims are under two PCT applications.
	GEM185	GLP-1/GIP dual agonist	Obesity, diabetes, NAFLD/NASH	s.c.	Peptide	Phase 1	1) GEM185 demonstrated the improvement of hyperglycemia in a clinical trial - Dual agonist for GLP-1R/GIPR is a validated target in treating diabetes and obesity - GEM185 is a potent dual agonist for GLP-1R/GIPR - GEM185 decreased glucose levels in patients with diabetes - Safe and well tolerated - Once daily dosing potential via injection - Weekly formulation is ongoing 2) R&D status - Phase 1 on-going - No longer available for licensing to Asia/Pacific excluding Japan.
	GEM172	Activation of multiple sulfatase	Multiple Sulfatase Deficiency	Oral / or injection	Small molecule	Preclinical – Phase 1 study in preparation	No effective treatment for the rare disease MSD is available. Combination of marketed drugs increase the activity of multiple sulfatases and significantly reduce toxic glycosaminoglycans in MSD fibroblast cell lines. Priority patent, which lead to global application, has been filed. Discussions are available for Japanese companies and Chinese companies.
	GEM046	Indirect activator of AMPK	Hyperlipidemia, type 2 diabetes, Cancer	Oral	Small molecule	Preclinical	Derivative of fungus product ascochlorin. Good PK profile in rats. Superior effects than metformin on blood glucose and triglyceride level in diabetic mice model. Significant enhancement of the efficacy in combination with metformin on T2D model Significant enhancement of the antitumor activity of anti-PD-1 antibody in mouse model

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM072	Orally available somatostatin analogues	Metabolic syndromes, Acromegaly, Hyperprolactinemia etc.*	Oral	Protein	Preclinical	The technology and "know-how" to synthesize somatostatin analogues which will be more potent, more specific, stable and orally available have been established. A few analogues (at lead generation/optimization stage) with different combination of receptor selectivity and differential hormonal secretion inhibition properties are available. *: Congenital hyperinsulinism, insulinomas, glucagonomas
	GEM077	AMPK activator	Topical fat accumulation	Transdermal or oral	Small molecule	Preclinical	A small molecular AMPK activator. It inhibited the growth of adipocytes in vitro and suppressed body weight and fat increases in vivo. Topical used formulation is under testing.
	GEM121	Modified phytic acid	Caner, Diabetes	Oral	Small molecule	Preclinical	•Anti-cancer activity including selective cytotoxic effect against T cell lines, apoptosis induction and inhibition of Akt activation in Jurkat cells, and reduction of the tumor volume in mice transplanted with ATL S1T cells. •Anti-diabetic activity enhancing AMPK activation, GLUT4 membrane translocation, glucose uptake in vitro, and lowering the blood glucose level of high-fat diet-induced obesity model mice
	GEM124	Improves endothelial cell function and cellular fluidity. Antiatherosclerotic, anti-inflammatory, anti-fibrotic, fat-targeting composition	1) Atherosclerosis (#) 2) Treatment of NASH (Stage F2-F3) Fibrosis with no worsening of fibrosis.	Oral	Small molecule	Preclinical	1) Developed to target vulnerable, high risk plaques while also reducing LDL cholesterol, increasing HDL cholesterol and reducing Triglycerides. (#) Future indications: primary prevention of Heart Attack, Stroke and Death and Secondary Prevention of Myocardial Infarction in Europe. US Patent to treat Atherosclerosis is valid until 2035. 2) Concurrently being developed to treat liver inflammation, fibrosis and fat accumulation while also reducing LDL cholesterol and Triglycerides. *May be used in combination with other drugs, such as Intercept's Ocaliva that increases Triglycerides or Gilead's NASH candidate that increases LDL cholesterol.
	GEM147	Insulin	Diabetes	Oral	Peptide	Preclinical	GEM147 is a nanoencapsulation of insulin in biodegradable polymer nanospheres. Nanoencapsulation protects insulin during stomach passage. In vivo, statistically significant reduction in blood glucose was seen in diabetic rats with oral GEM147 within 30 minutes.
	GEM150	Melanocortin 4 & 5 agonist	Obesity	Oral	Peptide	Preclinical	A pro-drug of the cyclic peptide (BL3020-1) which is a melanocortin 4 & 5 agonist showing good permeability in the gut and BBB and great reduction in food consumption and body weight gain in mice. The pro-drug did not show aggregation which BL3020-1 did. Currently the pro-drug is being optimized.
	GEM152	Fat-adsorption inhibitor	Obesity, Diabetes, Fatty liver	Oral	Natural product	Preclinical	Mushroom-derived natural product. Reduces weight gain and obesity, blood glucose and lipid contents in the liver via reduction of lipid absorption in the gut.

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	GEM203	FXR agonist and 5-HTR2A antagonist	NAFLD, Type 2 diabetes, obesity, dyslipidemia and hypertension	Oral	Small molecule	Preclinical	First in class single molecule having both FXR agonistic and 5-HTR2A antagonistic actions. In DIO mice, GEM203 reduced hyperglycemia, hyperinsulinemia, insulin resistance and liver lipid contents to similar or greater extent vs metformin. GEM203 reduced the body excess weight while metformin did not. In NASH model mice, GEM203 reduced liver excess weight, TG and TC contents, plasma ALT and AST, inflammation and collagen gene expression in the liver. Strong IP portfolio with long expiry dates granted in major markets.
	GEM228	GLP-1 with fatty acids bundles	Type2 Diabetes, obesity; NASH	s.c.	Peptide conjugated fatty acid	Preclinical	GEM228 -can be produced in high quality. -can lower blood glucose better than semaglutide and effectively control blood glucose level at 10 nmol/kg - can effectively reduce body weight and reduce liver fat
	GEM229	Insulin with fatty acids bundle	Type1/2 Diabetes	s.c.	Peptide conjugated fatty acid	Preclinical	GEM229 - can be produced in high quality and activate AKT phosphorylation as degludec. - can induce cell proliferation as degludec and inhibit cell apoptosis as degludec. -can better reduce blood glucose than degludec and effectively control blood glucose level at lower dosage than degludec. GEM229 shows better blood glucose control than degludec by once daily injection and better blood glucose control than degludec by every other day (Q2D) injection for 30 days. GEM229 causes a significant reduction in HbA1C level after treating for 60 days
	GEM234	Crosstalk of TGF-β signal and Wnt/β-catenin signal	Liver fibrosis, Nonalcoholic steatohepatitis, Kidney fibrosis, Renal fibrosis, Liver cancer, COVID-19	Injection	Small molecule	Preclinical	GEM234 is a novel small molecular which has suppressive effects on both hepatic stellate cell activation and kidney and liver fibrosis by suppressing TGF-β/Smad pathway via inhibition effect of Wnt/β-catenin pathway. GEM234 shows a higher suppressive effect on liver cancer stem cells than 5-FU. Wnt/β catenin inhibitors can block the infection of SARS-Cov-2, and GEM234 has potential to prevent occurrence of ARDS and cardiovascular damage in COVID-19.

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
Oncology: Hematological cancer	GEM164	Anthracycline topoisomerase II inhibitor	Breast cancer, Bladder cancer, Kaposi's sarcoma, lymphoma, and Acute lymphocytic leukemia	i.v.	Small molecule	Bioequivalence study completed	Generic pegylated liposomal doxorubicin hydrochloride. Doxorubicin is well known to cause cardiotoxicity and develop congestive heart failure. Cardiotoxicity of GEM164 is expected to be substantially lower than non-liposomal doxorubicin. Bioequivalence with CAELYX has been demonstrated.
	GEM036	Hematopoietic stem cell fucosylation	Prevention of infection & GvHD from hematopoietic stem cell transplantation	Infusion	Protein	Phase 3 ready with FDA SPA	In Phase 2 study: Statistically significant acceleration of immune system reconstitution (neutrophil/platelet recovery) Significantly reduced infection and GvHD Improved survival Positioned to be best-in-class No reports of adverse event specifically attributable to fucosylation
	GEM001	TRPV-1 agonist	Rheumatoid arthritis, Please refer to Note	Oral	Small molecule	Phase 2a	Updated on January 11, 2019 Potently inhibits TNF-a production by oral administration. Discontinued development for RA. Available for repositioning. Possible indications: Neuropathic pain, Crohn's disease, Systemic lupus erythematosus, Cachexia, Acute infectious disease, Allergy, Pyrexia, Anemia, Diabetes, Diseases related TNF-α (Colitis, Psoriasis ets.)
	GEM236	Nicotinamide phosphoribosyltransferase (NAMPT) inhibitor	Hematological (AML, ALL, lymphoma, MM) and some solid tumors (sarcoma, kidney, melanoma. etc.)	Oral	Small molecule	Phase 1/2a	-NAMPT is critical for the growth/survival of hematological cancers. -Synthetic small molecule structurally unrelated to NAMPT substrate or known inhibitors. -will be the First-In-Class drug. -Favorable pharmacological and toxicological profiles, showed no ophthalmic toxicity. -May increase susceptibility to other targeted cancer drugs (BCL-2, PARP, tyrosine kinase, proteasome, and HDAC inhibitors, anti-PD-1 antibodies) and DNA-damaging chemo/radiotherapy. Synergizes with tumor-specific mutations (IDH1/2, PPM1D, DNA repair deficiency). -Phase I study, which is near completion, demonstrated favorable toxicology profile with myeloid cells dose-limiting toxicity and signs of efficacy seen in several patients.
	GEM156	Chromatin destabilizing	Solid and hematological tumors	Oral, i.v., i.a	Small molecule	Phase 1	A First-In-Class chromatin destabilizing agent that intercalates into DNA, and interferes with histone/DNA binding changing its spatial structure. Consequent functional inactivation of a histone chaperon FACT leads to inhibition of several previously undruggable pro-cancer transcriptional factors, activation of p53 and interferon response. Dose-dependent nonclinical antitumor activity is seen in multiple models of solid and hematological tumors. Oral and i.v. phase 1 studies demonstrated a manageable safety profile and disease control with tumor regressions and protracted stable disease.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM046	Indirect activator of AMPK	Hyperlipidemia, Type 2 diabetes, Cancer	Oral	Small molecule	Preclinical	Derivative of fungus product ascochlorin. Good PK profile in rats. Superior effects than metformin on blood glucose and triglyceride level in diabetic mice model. Significant enhancement of the efficacy in combination with metformin on T2D model Significant enhancement of the antitumor activity of anti-PD-1 antibody in mouse model
	GEM050	Curcumin analogue	CML, Pancreatic cancer, Glioblastoma etc.	Oral	Small molecule	Preclinical	Inhibited proliferation of CML and pancreatic cancer cells at the submicromolar level. Unlike imatinib, the inhibitory action is irreversible. Suppressed almost completely human CML cell growth without significant changes in body weight and peripheral white blood cell count in vivo. An increase in ROS/RCS produced by inhibition of their scavenging enzymes is assumed to be involved in anti-tumor action. Induced M phase arrest.
	GEM065	Fucosylation of CAR-T cell and TCR-T cells to improve homing to tumors, increased intra-tumor penetration and killing of cancer cells. Potential for enabling CAR-T cell therapies to achieve higher response rates for treatment of blood cancers and also work for treatment of solid tumors	Lymphoma, Leukemia, Melanoma, Lung and breast cancers are initial indications	Infusion	Protein	Preclinical; Human safety and efficacy observed in stem cell transplantation	Ex-vivo fucosylation kit using proprietary recombinant fucosyl-transferase enzymes aimed at improving efficacy, safety and cost of care for T-cell therapy not only for treatment of blood cancers but also importantly, enabling CAR-T cell therapy to work in the treatment of solid tumors . Similar technology as in GEM036 for hematopoietic stem cell therapy, but a different fucosyl-transferase is used. Fucosylation enhances homing and intra-tumor penetration of CAR-T, TCR-T, TIL/CTL cells for improved tumor killing. Fucosylation does not affect healthy tissues.
	GEM121	Modified phytic acid	Caner, Diabetes	Oral	Small molecule	Preclinical	•Anti-cancer activity including selective cytotoxic effect against T cell lines, apoptosis induction and inhibition of Akt activation in Jurkat cells, and reduction of the tumor volume in mice transplanted with ATL S1T cells. •Anti-diabetic activity enhancing AMPK activation, GLUT4 membrane translocation, glucose uptake in vitro, and lowering the blood glucose level of high-fat diet-induced obesity model mice
	GEM134	Anti-CD147 antibody	Hematological (AML, MM etc.) and solid tumors (liver, colon, lung etc.)	i.v.	Antibody	Preclinical	Fully human antibody binding to human/ cynomolgus CD147. Has been shown to be very effective in various types of cancers in vivo xenograft mouse model. ADCC activity mainly contributes to the anti-tumor effect.

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	GEM206	FLT3 Kinase Inhibitor	Acute myeloblastic leukemia (AML)	Oral	Small molecule	Preclinical	- Novel chemical structure distinguished from known FLT3 inhibitors - Highly potent against FLT3 and FLT3 mutants (overcome FLT3-TKD mutation mediated drug resistant) - Highly selective - Monotherapy & orally active - Well-tolerance in preclinical tox study - GLP tox study is in progress.
	GEM238	CSN5 inhibitor	Cancer	i.v.	Peptide	Preclinical	- Identifying CDK2 binding regions within the CSN5 protein - Specifically inhibits the binding between CSN5 and CDK2 in "small complex" that is specifically expressed in cancer cells. - It is possible to specifically inhibit the growth of cancer cells while suppressing the effect on normal cells.
	GEM018	3rd generation immunotherapy technology	Cancer	s.c.	Protein	Discovery	Unique technology that triggers B and T cells simultaneously while activating all possible natural tumor killing mechanisms available to the immune-system. Tumor-directed specific activation reduces side effects to the minimum. Applicable on a target basis.
Oncology: Solid cancer	GEM164	Anthracycline topoisomerase II inhibitor	Breast cancer, Bladder cancer, Kaposi's sarcoma, lymphoma, and Acute lymphocytic leukemia	i.v.	Small molecule	Bioequivalence study completed	Generic pegylated liposomal doxorubicin hydrochloride. Doxorubicin is well known to cause cardiotoxicity and develop congestive heart failure. Cardiotoxicity of GEM164 is expected to be substantially lower than non-liposomal doxorubicin. Bioequivalence with CAELYX has been demonstrated.
	GEM157	Combined adoptive cell therapy (autologous)	Hepatocellular carcinoma (HCC)*	Infusion	Cell therapy	Launch	A combined adoptive cell therapy comprising cytokine-induced killer cells and activated cytotoxic T lymphocytes. In Phase III using patients whose tumors have been removed after curative resection for HCC, RFS was 44 months for the immunotherapy group while that of the control group was 30 months. The HR for tumor recurrence or death in the immunotherapy group vs the control group was 0.63. The mortality rate was reduced by 79% in the immunotherapy group vs the control group. Clinical trials for other solid tumors are ongoing. *: Adjuvant therapy for patients whose tumors have been removed after curative resection for HCC.
	GEM113	Bevacizumab biosimilar	Non-Squamous NSCLC	i.v.	Antibody	Phase 3	The profile of GEM113 is similar to Avastin, in peptide mapping, receptor binding affinity, inhibition of cell proliferation, in vivo xenograft mouse model, PK etc. Potential Indication: Metastatic Coloerectal Cancer; Recurrent Giloblastoma; Metastatic Renal Cell Carcinoma; Persistent Recurrent or Metastatic Cervical Cancer; Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

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	GEM208	A3 adenosine receptor (A3AR) agonist	Liver cancer* NAFLD**	Oral	Small molecule	Phase 3 in preparation* Phase 2 completed**	・A3AR is highly expressed in inflammatory and cancer cells. Specific agonists of A3AR induce apoptosis of cancer cells but not normal cells. ・Very good safety profile. ・An orphan drug status for hepatocellular carcinoma (HCC). ・In phase-2 study in HCC patients, it did not meet the primary endpoint (OS) but subgroup analysis of Child Pugh B patients showed a positive signal of efficacy for OS. ・In phase-2 study (vs placebo) in NAFLD/NASH, it met primary endpoint (liver enzyme) and reduced liver fat, fibrosis and steatosis..
	GEM159	Restoration of autophagy and reduction of inflammation	Breast cancer and other carcinomas*	Oral, intra-venous	Oligo-saccharides	Phase 2b/3 ready	A novel intestinally absorbable derivative (pat. pend.) of hydroxypropyl-α-cyclodextrin (HPαCD) that down-regulates the Phosphoinositide-system by controlling serum phospholipids and, thereby, reduces endocytosis. β CDs were effective in vivo against breast, ovarian, lung, and colon cancer, and metastatic melanoma, but need to be infused overnight and can cause permanent hearing loss. αCDs are not ototoxic and were more effective in vivo against growth and metastases of breast cancer. *Mono- or adjuvant treatment. 505(b)(2) is applicable.
	GEM001	TRPV-1 agonist	Rheumatoid arthritis, Please refer to Note	Oral	Small molecule	Phase 2a	Updated on January 11, 2019 Potently inhibits TNF-a production by oral administration. Discontinued development for RA. Available for repositioning. Possible indications: Neuropathic pain, Crohn's disease, Systemic lupus erythematosus, Cachexia, Acute infectious disease, Allergy, Pyrexia, Anemia, Diabetes, Diseases related TNF-α (Colitis, Psoriasis ets.)
	GEM008	Selective cMET inhibitor	NSCLC and HCC etc.	Oral	Small molecule	Phase 2	Effective on exon 14 skipping xenograft Development by an originator has been discontinued.
	GEM129	Immuno-modulator	Anogenital warts, Actinic keratosis, Basal cell carcinoma	Topical	Small molecule	Phase 2	· The first product on the market that combines the therapeutic benefits of a marketed immunomodulator with an innovative transparent bioadhesive film. · When applied to the lesion, generates a transparent bioadhesive film, which acts as a reservoir or matrix release and reduces the local reactions and increases the permanence of the product in the action site. · The results of non-clinical studies demonstrate that GEM129 has a better safety profile with an equivalent efficacy than its reference product. Clinical studies on-going.

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	GEM024	1. Selective inducer of apoptosis through modulation of NF-kB/P53 axis. 2. Eliciting adaptive immune response by recruitment of T Cells to tumors.	Oral Squamous Cell Carcinoma	Oral, pastille based topical delivery	Small molecule	Phase 2 ready	Updated on March 12, 2019 First-in-class, patented, combination therapeutic that simultaneously upregulates a cluster of genes promoting cell death and downregulates a cluster of genes promoting survival of cancer cells. Phase 1 results showed no significant AE, dose-dependent modulation of key biomarkers involved in disease pathogenesis, and T cell recruitment to tumor making it “hot”. FDA approved moving to Phase 2.
	GEM111	c-RAF allosteric inhibitor	Multiple cancers (lung, renal, liver etc.)	Oral	Small molecule	Phase 2 ready	A second generation (novel salt) of the c-RAF allosteric inhibitor in GEM 110 allowing for a more patient-centric dose profile. The clinical safety profile of GEM110 thus far will be informative and additive to the current clinical program thereby significantly de-risk and accelerate the clinical stage development of GEM111.
	GEM236	Nicotinamide phosphoribosyltransferase (NAMPT) inhibitor	Hematological (AML, ALL, lymphoma, MM) and some solid tumors (sarcoma, kidney, melanoma. etc.)	Oral	Small molecule	Phase 1/2a	-NAMPT is critical for the growth/survival of hematological cancers. -Synthetic small molecule structurally unrelated to NAMPT substrate or known inhibitors. -will be the First-In-Class drug. -Favorable pharmacological and toxicological profiles, showed no ophthalmic toxicity. -May increase susceptibility to other targeted cancer drugs (BCL-2, PARP, tyrosine kinase, proteasome, and HDAC inhibitors, anti-PD-1 antibodies) and DNA-damaging chemo/radiotherapy. Synergizes with tumor-specific mutations (IDH1/2, PPM1D, DNA repair deficiency). -Phase I study, which is near completion, demonstrated favorable toxicology profile with myeloid cells dose-limiting toxicity and signs of efficacy seen in several patients.
	GEM158	Anti-mitotic chemotherapy	Small cell lung cancer	i.v.	Small molecule	Phase 1 completed	Proprietary innovative albumin-stabilized pegylated liposomal docetaxel formulation. Elevated exposures of docetaxel compared with free (nonencapsulated) docetaxel were confirmed in animals and humans. Acceptable tolerability and results suggesting anti-tumor efficacy were observed in Phase 1. FDA orphan drug designation was granted and confirmed with FDA that 505(b)(2) NDA pathway appears to be an acceptable approach.
	GEM073	Kinase inhibitor of TGFβ-mediated phospho-SMAD2 signal transduction	COPD, IPF, Lung cancer	Oral	Small molecule	Phase 1	This kinase is selectively expressed in resident macrophages and airways epithelia of the lung and upregulated in COPD and IPF patients. A highly selective inhibitor showed efficacy across at least 3 different animal models relevant to COPD, IPF and NSCLC. Phase 1 trial has completed with a clean safety and tolerability profile.

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	GEM074	Dual inhibitor of Topo 1 and Topo 2	Drug resistant cancers	i.v.	Small molecule	Phase 1	1st-in-class combo therapy, covalently conjugated to simultaneously inhibit Topo 1 and 2, w/ EGFR cross-talk and extremely low toxicity for high dosing. Reduced tumor sizes w/ 38% CR and 98% TGI (compared to 0% and 33%, respectively, for imatinib) in CML xenograft models; and 98% TGI in colon cancer models at low doses. Showed immunotherapy enhancement effects with anti-PD-1 Ab and anti-CTLA-4 Ab with 100% CR in ovarian cancer model. No toxicity in rat & monkey models; No SAEs reported in Phase I at high dose 180mg/m2. Excellent PK profile and GI permeability of 9.2 enabling oral formulation.
	GEM110	c-RAF allosteric inhibitor	Multiple cancers (lung, renal, liver etc.)	Oral	Small molecule	Phase 1	The product is the combination of GEM110 and sorafenib. The product induces pDAPK and c-Raf to transfer from mitochondria to cytoplasm together with ROS increment resulting tumor cell death and demonstrated 73% and 57% tumor inhibition rate respectively in lung cancer and renal cancer animal xenograft model. FDA approved the clinical protocol to explore subjects by p-DAPK biomarker whose expression could be related with tumor progression.
	GEM115	Trastuzumab biosimilar-ADC	HER2-positive metastatic breast cancer	i.v.	Antibody	Phase 1	Conjugate of trastuzumab biosimilar and DM-1. The profiles of trastuzumab of GEM115 and GEM115 are similar to Herceptin and Kadcyla, respectively, in peptide mapping, receptor binding affinity, inhibition of cell proliferation, ADCC activities, in vivo xenograft mouse model, PK etc. Potential Indication: Early Breast Cancer (adjuvant)
	GEM122	Natural Killer T (NKT) cell-mediated anti-tumor responses	Solid cancer	i.v.	Cell therapy	Phase 1	GEM122 shows its anti-tumor activity by activating endogenous NKT cells. Activated NKT cells strongly enhance both innate and acquired immune systems, induce the long-term immune memory and promote accumulation of TILs (tumor infiltrating lymphocytes) in tumor sites. GEM122 consists of a novel NKT ligand and a novel APC. The novel NKT ligand shows much stronger NKT activity than the previous NKT ligand, α-Galactosylceramide and by using the novel APC, the cellular product can be manufactured efficiently as well.

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	GEM126	Selective estrogen receptor downregulator	ER+ advanced or metastatic breast cancer	Oral	Small molecule	Phase 1	• Both antagonizes and degrades ER alpha in cells to achieve the goal of blocking the estrogen signaling pathway. • Favorable oral pharmacokinetics in healthy rats and dogs whereas fulvestrant has a low bioavailability and can only be intramuscularly administrated. • Favorable preclinical in vitro and vivo single agent efficacy in inhibiting ER+ breast cancer cell proliferation, in models of tamoxifen-sensitive and tamoxifen-resistant breast cancer. • Highly selective, no effect on other kinases and receptors. • Can be licensed to global area with some limitation.
	GEM156	Chromatin destabilizing	Solid and hematological tumors	Oral, i.v., i.a	Small molecule	Phase 1	A First-In-Class chromatin destabilizing agent that intercalates into DNA, and interferes with histone/DNA binding changing its spatial structure. Consequent functional inactivation of a histone chaperon FACT leads to inhibition of several previously undruggable pro-cancer transcriptional factors, activation of p53 and interferon response. Dose-dependent nonclinical antitumor activity is seen in multiple models of solid and hematological tumors. Oral and i.v. phase 1 studies demonstrated a manageable safety profile and disease control with tumor regressions and protracted stable disease.
	GEM181	Selective HDAC8 inhibitor	Solid tumor	Oral	Small molecule	Phase 1	Through several mechanisms exhibited tumor inhibitory activity against many cancers, especially with high HDAC8 protein expression. Advantages of GEM181 - Able to pass the BBB - Suppresses angiogenesis - Side effects less than those of currently marketed drugs - Simple synthetic method
	GEM189	Nanoliposome-encapsuled Radionucleotide	*Recurrent Glioblastoma, **Multiple tumor	Intratumoral	Radionucleotide	*Phase1, **Preclinical	Radionuleotide in GEM189 is ideal one for the treatment of solid Tumors. It delivers a high dose of radiation directly to the tumor while sparing normal, healthy brain tissue, stays at the tumor for several days and Effect lasts for several days and then dissipates. No serious adverse events observed to date. Key advantages over External Beam Radiation Therapy: -At least 500 Gy, -Single 4-day hospitalization -Able to more effectively treat tumor margins - Limited toxicity -Able to verify successful delivery with SPECT scan

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	GEM035	An anti-ENO1 antibody	Immune diseases, Various cancers	s.c.	Protein	US FDA IND cleared	GEM035 is a humanized antibody against unique ENO1 target. This therapeutic antibody is first-in-class to target inflammatory macrophage and demonstrates efficacy in animal models of MS, IPF, and IBD. It also showed efficacy in animal models of lung, pancreatic, and prostate cancer, most likely by targeting tumor associated macrophage (TAM). GEM035 may be developed for treatment of COVID-19 induced ARDS based on its capability to suppress macrophage related immune response. GEM035 has a worldwide patent protection. US IND of GEM035 is approved and active now for treating MS.
	GEM066	Selective STAT3 inhibitor (DNA-based Decoy)	Head and neck squamous cell carcinoma and Non-small cell lung cancer (including exon 20 mutations)	i.v.	Nucleic acid	Pre-IND for systemic administration formulation	1st-in-class STAT3 decoy; Suppresses binding of STAT3 to genomic DNA; Inhibits proliferation and promotes apoptosis of many cancer cells; Suppresses expression of STAT3 target genes and tumor growth in animal models; Shows increased response in combination with cetuximab and also with PD-1; Human Phase 0 study (intratumor injection); Suppresses STAT3 target genes expression with one dose Does not affect normal oral keratinocytes; Exploratory animal toxicology studies show no significant adverse effects
	GEM174	Invadopodia-Targeted siRNA	Advanced and/or highly metastatic cancers*	i.v.	Nucleic acid	Pre-IND	Invadopodia mediates cancer cell invasion, intravasation and extravasation. Master Invadopodial Regulators (MIRs) are the driver genes of cancer invasiveness and metastasis and are rarely expressed by normal cells. MIR-1 is also a cardinal regulator of Wnt activity and tumor growth. GEM174 is a lipid nanoparticles-formulated siRNA specifically targeting MIR-1. GEM174 suppressed many tumor growth and extended survival time in xenograft model. *hepatocellular carcinoma, triple-negative breast cancer, and gastric adenocarcinoma
	GEM009	BET inhibitor	Cancer, RA	Oral	Small molecule	Preclinical	Updated on January 11, 2019 More potent enzyme inhibition and anti-tumor activities compared with competitors (more potent than GSK525762A and comparable to ABBV-075). Superior safety profile than competitors (no inhibition on hERG or CYP3A4) and can be applied to RA. Easier manufacturing due to absence of asymmetric carbon.
	GEM019	3rd generation immunotherapy targeting HER2	HER2 overexpressing cancer (Breast)	s.c.	Protein	Preclinical	Applied 3rd generation immunotherapy technology to HER2. Superior efficacy to trastuzumab and pertuzumab. In-vivo PoC has been validated in non-human primates.

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	GEM020	3rd generation immunotherapy targeting little gastrin	Gastro-intestinal cancer (Pancreatic)	s.c.	Protein	Preclinical	Applied 3rd generation immunotherapy technology to little gastrin. In-vivo POC has been validated in non-human primates.
	GEM025	miRNA suppressing the expression of a protein characteristic of pancreatic cancer stem cells	Pancreatic cancer	i.v.	Nucleic acid	Preclinical	Excellent antitumor effect was demonstrated in uniquely established pancreatic cancer stem cell model in vitro and in vivo.
	GEM026	siRNA suppressing the expression of novel cancer stem cell gene "Gene A"	Cancer	i.v.	Nucleic acid	Preclinical	Novel cancer stem cell gene "Gene A", which was discovered by single cell analysis of cancer stem cell, shows character as follows. 1.Superior cancer stem cell diagnostic marker than known cancer stem cell marker CD44v9 2.SiRNA targeting Gene A demonstrate excellent antitumor effect with current medicines.
	GEM027	miRNA targeting refractory colon cancer with mutated K-ras	Colon cancer	i.v.	Nucleic acid	Preclinical	The miRNA regulates EGFR signaling pathway by directly inhibiting of both KRAS and AKT1 and demonstrate excellent antitumor effect in vitro and in vivo.
	GEM028	miRNA targeting refractory colon cancer with mutated K-ras and refractory pancreatic cancer	Pancreatic cancer, Colon cancer	i.v.	Nucleic acid	Preclinical	The miRNA regulates K-ras, Bcl2, survivin, and NF-kB and demonstrate excellent antitumor effect in vitro and in vivo.
	GEM050	Curcumin analogue	CML, Pancreatic cancer, Glioblastoma etc.	Oral	Small molecule	Preclinical	Inhibited proliferation of CML and pancreatic cancer cells at the submicromolar level. Unlike imatinib, the inhibitory action is irreversible. Suppressed almost completely human CML cell growth without significant changes in body weight and peripheral white blood cell count in vivo. An increase in ROS/RCS produced by inhibition of their scavenging enzymes is assumed to be involved in anti-tumor action. Induced M phase arrest.

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM065	Fucosylation of CAR-T cell and TCR-T cells to improve homing to tumors, increased intra-tumor penetration and killing of cancer cells. Potential for enabling CAR-T cell therapies to achieve higher response rates for treatment of blood cancers and also work for treatment of solid tumors	Lymphoma, Leukemia, Melanoma, Lung and breast cancers are initial indications	Infusion	Protein	Preclinical; Human safety and efficacy observed in stem cell transplantation	Ex-vivo fucosylation kit using proprietary recombinant fucosyl-transferase enzymes aimed at improving efficacy, safety and cost of care for T-cell therapy not only for treatment of blood cancers but also importantly, enabling CAR-T cell therapy to work in the treatment of solid tumors . Similar technology as in GEM036 for hematopoietic stem cell therapy, but a different fucosyl-transferase is used. Fucosylation enhances homing and intra-tumor penetration of CAR-T, TCR-T, TIL/CTL cells for improved tumor killing. Fucosylation does not affect healthy tissues.
	GEM068	Gene therapy for novel target	Lung and other cancers	i.v.	Nucleic acid	Preclinical	The expression of this gene is reduced in various cancers. Adenovirus expressing this gene inhibits the HIF-1α expression and proliferation of various cancer cells. Adenovirus expressing this gene suppresses growth of lung cancer in nude mice.
	GEM069	Immuno-modulator (adjuvant)	Vaccine, Cancer immunotherapy etc.	Injection	Other	Preclinical	*E.coli* producing monophosphoryl Lipid A whose structure is similar to existing adjuvants such as MPL and GLA. Shows similar efficacy with MPL in vitro and in vivo. Lower cost production through simple fermentation and purification steps
	GEM071	Nanoparticle formulation of 2-deoxy-glucose	Hepatocellular carcinoma, Renal cancer, Colorectal cancer	i.v.	Small molecule	Preclinical	In the xenograft model, the administration of nanoparticle formulation once a week showed superior antitumor effect than daily administration of 2-deoxyglucose alone. No side effects were observed. Enhanced the antitumor effect by combination with existing anticancer drugs. Enhanced T cell infiltration into tumor tissue. The substrate used in the nanoparticle formulation are used in approved medicines (FDA).
	GEM078	Hyaluronic acid-based nanocarriers of cisplatin	Head and neck cancer, Pancreatic cancer, Melanoma with metastasis	i.v.	Small molecule	Preclinical	CD44 targeting and higher stability lead to enhance lymphatic delivery and inhibit cancer with lymphatic metastasis. Chemodrug encapsulated by nanocarriers minimize systemic toxicities. Convenient dosing by intravenous injection.
	GEM085	Cancers with moderate to high Her2 expression	Cancers with moderate to high Her2 expression	i.v.	Protein	Preclinical	The anti-Her2 ADCs consisting of trastuzumab and novel linker-drugs. - 10-100 fold higher potency comparting to Kadcyla® - High therapeutic window (MED ~1-2 mg/kg, MTD ~100 mg/kg in mice) - High tumor growth inhibition rate (90-100%) with high stability in vivo

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM102	Cyclodextrin derivative	Cancer	i.v.	Small molecule	Preclinical	Modified Methyl-b-Cyclodextrin (CyD). Displayed potent antitumor activity in vitro, compared to M-β-CyD. Drastically inhibited tumor growth after a single intravenous injection to tumor-bearing mice, compared to doxorubicin and M-β-CyD, without any significant change in blood chemistry values.
	GEM123	miRNA targeting cancer stem cells	Colon cancer	i.v.	Nucleic acid	Preclinical	GEM123 suppressed the stemness of cancer cells by inhibiting KLF5 expression, and provoked apoptosis and cycle arrest through the downregulation of TFDP1and MDM2 expressions. GEM123 also inhibited tumor growth with no apparent side effect in mouse model.
	GEM134	Anti-CD147 antibody	Hematological (AML, MM etc.) and solid tumors (liver, colon, lung etc.)	i.v.	Antibody	Preclinical	Fully human antibody binding to human/ cynomolgus CD147. Has been shown to be very effective in various types of cancers in vivo xenograft mouse model. ADCC activity mainly contributes to the anti-tumor effect.
	GEM136	Biosimilar trastuzumab	Same indications as trastuzumab	i.v.	Antibody	Preclinical	GEM136 N-terminal sequences are identical to trastuzumab. Levels of contaminating proteins, profiles of breakdown products and inhibitory activity to trastuzumab on in vitro growth of hER2 positive breast cancer cell line are similar between GEM136 and trastuzumab. Plant-based technology (TGEM036) was applied for production of GEM136.
	GEM146	VD Receptor	Prostate cancer, Autoimmune diseases	i.v.	Small molecule	Preclinical	GEM146 is a nanosomal formulation of a nontoxic Vitamin D3 analog. In vivo studies have shown strong anticancer effects of GEM146 against Hormone Refractory Prostate Cancer xenografts in nude mice at doses approximately 6.5 times less than the parent hormone, without significant toxicity.
	GEM176	A new anti-angiogenesis drug	Solid tumor* and Retina disorder **	Injection	Protein	Preclinical	Best-in-class product against anti-VEGF agents The fusion protein of the second domains from VEGF receptor-1 and the Fc portion of human IgG1. Higher avidity for VEGF/PLGF and low immunogenicity and side effect. *More complete blockade of Tumor growth. (pancreatic cancer, liver cancer, gastric cancer, non-small cell lung cancer) **Longer duration of action (wet AMD, Diabetic macular edema, retinal vein occlusion, diabetic retinopathy)

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM167	Elimination of MADD protein	Solid tumors	i.v., intra-tumoral	Gene therapy	Preclinical	A systemically deliverable oncolytic viral vector to target and eliminate the MADD protein overexpressed in a wide range of human cancer cell lines and involved in resistance. Systemic delivery demonstrated to colon, breast, liver, and ovarian tumors with no liver or kidney damage. Our parental vector infects and replicates only in cancer cells and has undergone extensive distribution and toxicity studies in mice and baboons and was previously approved for human trials. Breast, liver, and anaplastic thyroid cancer using siRNA achieved 41-60% TGI as mono or combo therapy.
	GEM195	A potent DNA-immunotherapy for MAGE A	Triple Negative Breast Cancer (TNBC)	Intramuscular Injection	DNA Plasmid	Preclinical	DNA vector with MAGE A inserted into our original platform (TGEM052) and delivered into muscle cells using intramuscular injections followed by electroporation. The plasmid moves into nucleus of muscle cells and starts to over-express MAGE A, eliciting an immune response that can target MAGE A on cancer cells and destroy them.
	GEM205	Anti-Mesothelin (MSLN) Antibody-Drug Conjugate (ADC)	Cancer (Pancreatic Cancer, Ovarian Cancer etc.)	Injection	Antibody	Preclinical	- Mesothelin is a differentiation antigen overexpressed in many solid tumors - GEM205 showed great tumor growth inhibition (>90%) in animal model without body weight loss. - GEM205 also showed great efficacy in large tumor model (>500 mm3). - Self-owned I4 technology was applied in GEM205. - GEM205 showed uniform DAR (4), high affinity, good cytotoxicity.
	GEM213	Anti-CSF-1R antibody	Cancer, PVNS (pigmented villonodular synovitis)	i.v.	Antibody	Preclinical	GEM213 is an antibody with high affinity and neutralizing ability. - GEM213 can potently inhibit Colony Stimulating Factor Receptor 1 (CSF-1R) in cellular contexts and has the potential to induce a therapeutic effect on macrophages. - GEM213 has unique CDR sequences and epitopes. - GEM213 is a promising new agent with potential to combine with immune checkpoint inhibitors to relief macrophage-dependent immune suppression and would yield clinical benefit.
	GEM218	Anti- Human PD-L1 antibodies	Cancer	i.v.	Antibody	Preclinical	GEM218 is a novel monoclonal antibody that specifically binds to PD-L1 with high affinity and effectively blocks PD-1/PD-L1 interaction. - Can be well detected by the PD-1/PD-L1 Blockade Assay. - Novel binding epitopes. - Good potential for a companion diagnosis. - The efficacy and toxicity are studied in various in vitro and in vivo models.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM219	Anti-TIM-3 antibody	Cancer	i.v.	Antibody	Preclinical	GEM219 is a fully human anti-TIM-3 antibody with high affinity in vitro and cell-based binding assay. - The anti-TIM-3 antibodies are also highly functional in cellbased bioassay. - Some anti-TIM-3 antibodies have cross-species recognition ability to mouse TIM-3. - Animal efficacy studies are in progress
	GEM220	Anti-Globo H Antibody	Breast Cancer	i.v.	Antibody	*Preclinical **Discovery	* Anti-Globo H monolonal antibody - Higher patient population in breast cancer (61%). - Anti-cancer efficacy demonstrated in breast cancer animal model through ADCC and CDC. **Anti-Globo H bispecific antibody - High correct pairing (>95%) -Target cell-dependent T cell activation (Better safety profile). - Anti-cancer efficacy demonstrated in breast cancer animal model through T cell-mediated cytotoxicity.
	GEM221	Anti-Globo H ADC	Cancer	i.v.	Antibody	Preclinical	High affinity, fast internalization, good in vitro cytotoxicity - Showed great tumor growth inhibition (>90%, 3 mg/kg) in HCC-1428 animal models without any body weight loss - Can be prepared reproducibly at gram scale.
	GEM225	Regulating the cellular pat	Triple negative breast cancer, Pancreatic cancer	i.v.	Protein	Preclinical	- GEM225 is a recombinant human KL-1 (rhKL-1). - KL-1 is the domain with the anti-cancer activity of Klotho, a hormone with tumor suppression activity. - Klotho expression in epigenetically silenced in malignant tissues. - rhKL-1 inhibited tumor growth in-vivo. - rhKL-1 demonstrated acceptable safety profile in the in-vivo studies. - rhKL-1 can provide effective and safe solution where currently approved treatments fail.
	GEM230	Anti-CD38 scFv-Fc conjugation of lenalidomide	Multiple Myeloma	i.v.	Antibody-drug conjugates	Preclinical	GEM230 - The conjugation does not affect cell binding affinity compared to parental antibodies. - Conjugation with lenalidomide bundle did not affect ADCC/CDC activities on CD38+ cells - In the multiple myeloma xenograft mouse model, GEM230 has superior tumor suppression ability compared to parental antibody, Darzalex.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM232	Anti-soluble MICA/MICB antibody	Prostate Cancers (mCRPC), other cancers	i.v.	Antibody	Preclinical	- GEM232 is a humanized antibody specific for soluble NKG2D ligands MICA and MICB, which are multi-mechanistic suppressors of the immune system that become upregulated in cancer but are normally absent. - GEM232 binds non-membrane bound MICA/B (shed/soluble forms) but not cell surface attached versions, thereby offering safety benefits such as avoiding autoimmunity. - Antibody binding may help prevent immunosuppression and may enhance NK and CD8+ T cell activation mediated by the NKG2D receptor leading to tumor cell killing. Both arms of immune system (innate and adaptive) can be impacted. - Significant tumor inhibition demonstrated using prostate xenografts in both immune compromised mice and in mice with humanized immune systems (hPBMC), with no observable toxicity. A unique epitope has been identified for this high affinity antibody.
	GEM238	CSN5 inhibitor	Cancer	i.v.	Peptide	Preclinical	- Identifying CDK2 binding regions within the CSN5 protein - Specifically inhibits the binding between CSN5 and CDK2 in "small complex" that is specifically expressed in cancer cells. - It is possible to specifically inhibit the growth of cancer cells while suppressing the effect on normal cells.
	GEM259	A novel peptide targeting a STAP-2-EGFR	Prostate cancer, Breast cancer	i.v.	Peptide	Preclinical	STAP-2 belongs to a family of STAP adaptor proteins and plays a crucial role in a variety of cellular signal transduction pathways. STAP‐2 is expressed in various cancer cell lines and the expression level is higher than normal cells. The inhibition of STAP-2 and EGFR interaction could be a novel target for the treatment of cancer. A novel peptide inhibiting STAP-2/EGFR interaction shows anti-tumor efficacy in vitro and in vivo.
	GEM261	A novel PPM1D inhibitor	Cancer	p.o.	Small molecule	Preclinical	Protein phosphatase Magnesium-dependent 1, Delta (PPM1D)/ Wip1 is a wild-type p53-inducible Ser/Thr phosphatase that acts as a negative regulator of the p53 tumor suppressor. Gene amplification and overexpression of PPM1D have been reported in various cancers including leukemia and neuroblastoma. A novel PPM1D/WIP1 inhibitor suppresses medulloblastoma and neuroblastoma growth *in vivo* .

Drug candidates by Disease Area

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As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM264	Keytruda Biosimilar	Including, but not limited to, Renal cell carcinoma, Cervical cancer, Esophageal Stomach cancer, Non–small cell lung cancer, Melanoma	i.v.	Antibody	Preclinical, head-to-head similarity study completed	The cell line development, cell banking and characterization, process development of GEM264 were completed. The production processes have been successfully scaled up to four 200L runs. The head-to-head similarity study indicated that of GEM264's drug product physicochemical quality is similar or highly similar to that of EU-, US-, and China-sourced Keytruda®. GEM264's tumor growth inhibitory activity, competitive binding, blockade assay, and PK profile are also highly similar to that Keytruda®.
	GEM018	3rd generation immunotherapy technology	Cancer	s.c.	Protein	Discovery	Unique technology that triggers B and T cells simultaneously while activating all possible natural tumor killing mechanisms available to the immune-system. Tumor-directed specific activation reduces side effects to the minimum. Applicable on a target basis.
	GEM215	Globo H-Specific CAR-T Cells	Solid Tumor: breast cancer, gastric cancer and lung cancer	i.v.	Cell therapy	Discovery	Potential cell therapy for Globo H+ solid tumor. -Combination with anti-PD-L1 Ab overcomes PD-L1-mediated immune suppression on CAR-T cells in tumor microenvironment. -Anti PD-L1 Ab is able to induce bystander effect during Globo H CAR-T cell treatment.
	GEM242	Anti-Globo H x CD3 bispecific antibody	Breast cancer	i.v.	Antibody	Discovery	GEM242 has high correct pairing property (>95%) It also possesses target cell-dependent T cell activation property. Anti-cancer efficacy has been demonstrated in the breast cancer animal model through T cell-mediated cytotoxicity. (>83%, 10mg/kg)
Oncology: Supportive care	GEM145	5-HT	Chemotherapy Induced Nausea and Vomiting (CINV)	Oral	Small molecule	Phase 2/3	Acute vomiting was blocked effectively by 5-HT3 anti-emetics plus the adjuvant Emend® but no benefits were observed in terms of the incidence of nausea . Phase 2/3 clinical trial on GEM145 as an adjuvant to conventional 5-HT3 anti-emetics was completed (more than 600 cancer patients). All doses of GEM145 significantly reduced acute nausea severity compared to the placebo (p=0.003).
	GEM083	Vasoconstriction and anti-inflammatory action	Hemorrhagic cystitis	Topical (Intravesical)	Small molecule	Phase 2	Pre-liposomal lyophilate containing tacrolimus. POC achieved in animal models of both chemo-cystitis and radiation cystitis. POC achieved in first-in-man experience treating severe recurrent hemorrhagic cystitis. Orphan drug designation granted.

Drug candidates by Disease Area

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As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM059	Recombinant Human Interleukin-1 Receptor Antagonist	Please refer to Note	IM	Protein	Phase 1	Indication: 1: Infection, as manifested by febrile neutropenia, in patients with malignancies receiving chemotherapy drugs. 2: Diarrhea in patients with malignancies receiving chemotherapy drugs. 3. Gout arthritis Note: The world's first multiorgan protection agent for tumor chemotherapy. Inhibits cell cycle progression of normal cells and renders them resistance to chemotherapy. No effects on tumor growth and their sensitivity to chemotherapy Phase 1 : No dose limiting toxicity, None of subjects presented grade 3 or above chemotherapy-induced neutropenia or diarrhea. Gout arthritis: Well tolerated and safe for patients who are restricted from NSAID, glucocorticoid, or colchicine.
	GEM223	IP6K inhibitor (Inhibition of cellular phosphate export and regulation of intracellular energy status)	Cancer chemotherapy-associated hyperphosphatemia, Chronic kidney disease-associated hyperphosphatemia	Oral Intravenous	Small molecule	Pre-IND	1) Originator identified a new MOA that IP6K inhibition as a new mechanism in lowering circulating phosphate - IP6K has a physiological role in regulating circulating phosphate and intracellular ATP levels - GEM223 is an in vivo effective IP6K inhibitor with a first-in-class potential - A robust therapeutic effect in improving hyperphosphatemia and ameliorating organ function were observed in preclinical settings - Four-week toxicological studies were completed in rats and monkeys (Additional studies may be conducted depending on target disease) - Originator considers to discuss with a potential partner for the initiation of a first-in-human study (Funding, collaboration, and out-licensing) 2) Potential target diseases - Chronic kidney disease-associated hyperphosphatemia (No clinical phosphate lowering drug has kidney protective effect), tumor lysis syndrome (No efficient drug is available in tumor lysis syndrome-associated hyperphosphatemia) 3) R&D status

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM143	CB1, CB2, 5-HT1a	Multiple Sclerosis (MS), Opioid addiction, Chemotherapy induced Peripheral Neuropathic Pain (CIPNP), and Epilepsy	Oral	Small molecule	Preclinical	GEM143 is a nanoencapsulation of the API in biodegradable polymer nanospheres for improved oral bioavailability. MS: The API has multiple actions on key molecular neuroinflammation and neurodegeneration targets, with highly effective in vitro and in vivo bioactivities. Opioid addiction: The API is not an opioid and has been shown to alleviate cue-induced opioid addiction behaviors and allosterically modulate the μ and δ-opioid receptors. CIPNP: Nanoencapsulation is being used to protect the API during the stomach passage. Epilepsy: The API is an effective anti-convulsant with a specificity more comparable to drugs clinically effective in major seizures.
	GEM250	Antisense oligo nucleotide (ASO) suppressing the expression of human p53 gene	Drug-induced alopecia	Topical	Nucleic acid	Discovery	Suppression of p53 expression may reduce the tissue damage and enhance tissue repair in several disease conditions. It inhibits p53 expression better than the competitor compound in cultured cell, and is therefore expected to be highly effective in clinical practice.
Ophthalmology	GEM231	JNK inhibitor	Dry Eye, Dry and Wet AMD, Uveitis, Chronic inflammation alternative to Steroids (* see note)	Intravitreal, Subconjuncti-val, Drops	Peptide	・Clinical Phase 3 (acute post surgery) ・Preclinical (Other indications)	・Potent and selective non-ATP competitive hJNK2 and hJNK3 inhibitor ・Full D amino acids – TAT peptide with high resistance to proteases and highly soluble in saline ・Coupled to a carrier sequence that selectively delivers it into the cell ・Excellent safety and toxicology profile (therapeutic indexes in 100 - 1000 range) ・Administered to 1000+ patients to date with no sign of intolerance (through subconjunctival single dose administration) ・Excellent patent position ・Simple to manufacture at low COG per dose *Current pre-clinical studies indicate those potential areas for developments
	GEM067	c-Kit inhibitor	Diabetic macular edema & Retinopathy	Oral	Small molecule	Phase 2a completed	Inhibits stem cell factor-induced hyperpermeability Reverses retinal vascular leakage in STZ-induced diabetic rats Improved compliance to administration (oral) than anti-VEGF therapy (intra-vitreal injection) Applicable to non-responders to anti-VEGF therapy Repositioning of a marketed drug

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM254	Stem cell repairing	Dry eye syndrome	Topical (eye drop)	Peptide	Phase 2	Synthetic PEDF-derived short peptide to stimulate proliferation and differentiation of corneal limbal stem cells to speed up cornea repair process. Repair severe cornea damages for patients lacking treatment options. The Phase 2 studies demonstrated that GEM254 is safe, effective, and the results are reproducible. Long patent protection. Available for licensing globally excluding China.
	GEM175	Elevates RPE phagocytic function to clear retinal drusen (lipoprotein deposits) and reduce oxidative stress	Intermediate AMD	Oral	Small molecule	Phase 2 ready	Novel high-dose reformulation of statin previously marketed as a lipid lowering drug, now developed for the new use of treating intermediate AMD. POC clinical trial showed a marked clearance of drusen and a 75% reduction in progression to late AMD (CNV/GA). Abbreviated 505(b)(2) pathway. Patent applications have been made globally.
	GEM114	Ophthalmic formulation of GEM113	Wet AMD	Intravetreal	Antibody	Phase 1	GEM114 mainly distributed in retina, vitreous body and aqueous humor after intravetreal injection in animals. Potential Indication: Diabetic Macular Edema; Myopic Choroidal Neovascularization (mCNV); Retinal Vein Occlusion (RVO); Diabetic Retinopathy (DR)
	GEM155	FPR2-specific ligand	Atopic dermatitis/Psoriasis, Dry eye disease, IBD (Inflammatory bowel disease), Asthma, Rheumatoid arthritis	Topical, Eye drop, s.c.	Peptide	Phase1	GEM155 is a small (7mer) lipidated peptide ligand for pro-resolving receptor FPR2 (N-formyl peptide receptor 2) involved in regulation of innate immune system and inhibition of ILC2 function (adaptive immune system). It also has anti-microbial effect for pathogenic bacteria through fusion with functional moiety. Efficacy is seen in animal models for the indications. CMC study is almost done. Toxicity study for topical usage and subcutaneous injection is going-on. Formulation for topical use is almost finished.
	GEM255	Stem cell repairing	Neurotropic keratitis	Topical (eye drop)	Peptide	Phase 1	Synthetic novel neurotrophic PEDF-derived short peptide that stimulates wound healing and corneal repair. Effectively regenerate healthy limbus after extensive limbal layer removal (Rabbit Model) Long patent protection.Available for licensing globally.
	GEM140	Limbal stem cells	Intractable limbal stem cell deficiency	Cell therapy	Implantation	Clinical	Establishment and production of limbus-derived epithelial cell plate manufacturing process in GMP facility with excellent economic feasibility. Phase 1 study is currently in progress.
	GEM086	VEGF inhibitor	Wet AMD (age-related macular degeneration)	Topical (eye drop)	Small molecule	Preclinical	New formulation of axitinib designed to deliver the drug across ocular tissues to choroid and retina. -Greatly enhancing aqueous solubility (4000-fold solubility enhancement) - High drug exposure in retina (300-fold of IC50) - Potential for substitution of anti-VEGF Ab treatment via intravitreal injection

Drug candidates by Disease Area

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	GEM087	Corticosteroid receptor agonist	Ocular inflammation and Meibomian gland dysfunction (MGD)	Topical (eye drop)	Small molecule	Preclinical	New ophthalmic suspension of loteprednol etabonate (LE) with improved ocular bioavailability. - Drug exposure in aqueous humor and iris ciliary body are about 6 fold higher than Lotemax® in rabbits. - The new formulation of LE administered twice a day for the treatment of adjuvant induced chronic uveitis model in rabbits showed a similar efficacy with lotemax administered four times a day
	GEM137	Biosimilar ranibizumab	Same indications as ranibizumab	Intra-vetreal	Antibody	Preclinical	Peptide mapping by Mass Spectrometry confirms amino acid sequence identity of GEM137 with ranibizumab. Purified GEM137 is highly similar to ranibizumab by SDS-PAGE. Ligand (rVEGF) biding by GEM137 demonstrated to be similar to ranibizumab by ELISA. Plant-based technology (TGEM036) was applied for production of GEM137.
	GEM138	Biosimilar adalimumab	Same indications as adalimumab	i.v.	Antibody	Preclinical	Purified GEM138 is highly similar to adalimumab by SDS-PAGE. GEM138 and adalimumab show a similar response in a TNF-a ELISA assay. Plant-based technology (TGEM036) was applied for production of GEM138.
	GEM176	A new anti-angiogenesis drug	Solid tumor* and Retina disorder **	Injection	Protein	Preclinical	Best-in-class product against anti-VEGF agents The fusion protein of the second domains from VEGF receptor-1 and the Fc portion of human IgG1. Higher avidity for VEGF/PLGF and low immunogenicity and side effect. *More complete blockade of Tumor growth. (pancreatic cancer, liver cancer, gastric cancer, non-small cell lung cancer) **Longer duration of action (wet AMD, Diabetic macular edema, retinal vein occlusion, diabetic retinopathy)
	GEM177	BOTOX Biosimilar	Refer to Note	Injection	Protein	Preclinical	Equivalent efficacy and similar safety profile (for biosimilar for Allergan Botox) Manufacturing using plant-derived mediums Indication - Therapeutic applications: strabismus, cerebral palsy, cervical dystonia, neurogenic bladder, migraine, facial spasm, blepharo spasm - Aesthetic application: all wrinkles produced due to persistent muscular contractions, square jaw reduction, hyperhidrosis
	GEM188	Dual inhibitor of ROCK and new target kinase	Glaucoma; ocular hypertension	Small molecule	Topical eye drop	Preclinical	GEM188, a dual ROCK/new target kinases inhibitor, had shown more effective in intraocular pressure lowering than competitor netarsudil in magnetic bead-induced and hypertonic saline-induced ocular hypertensive models. Moreover, GME188 also showed lower eye irritation than netarsudil in New Zealand White rabbit. The plasma exposure by eye drops dosing was less than that by iv dosed with NOAEL. The preclinical studies including GMP-compliance production, GLP toxicology, etc., is ongoing in 2020.

Drug candidates by Disease Area

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Orthopedic	GEM106	Osteoblasts for bone regeneration	Avascular necrosis/Osteonecrosis	Interventional Implantation	Cell therapy	Launch	Live cultured osteoblasts indicated for bone repair and regeneration that stop the progression of avascular necrosis. Over 800 patients were treated with GEM106. Potential label extension to different indications. This product has been granted Orphan Designation by the US FDA & EMA.
	GEM107	Chondrocytes for hyaline cartilage regeneration.	Articular cartilage defects	Interventional Implantation	Cell therapy	Launch	Live cultured chondrocytes indicated for hyaline cartilage regeneration in cartilage injuries. Over 700 patients treated with several publications and patent protection.
	GEM237	Autologous chondrocyte cell therapy for cartilage repair/regeneration	Chondral and osteochondral articular lesions of the knee	Arthroscopic implantation	Cell and scaffold	Launch	The autologous cartilage repair system (a device kit consisting of a bioabsorbable highly porous scaffold and an enzyme for processing removed a small amount of cartilage) is for one-step surgery. It does not require an *ex vivo* cell expansion process. Hyaline cartilage is regenerated and long-term effectiveness is superior to the marrow stimulation procedure.
	GEM105	Viscosupplementation	Knee osteoarthritis	Intraarticular	Poly-saccharide	Marketing authorization	Cross-linked sodium hyaluronate hydrogel with sodium hyaluronate fluid. Long-lasting and sustainable efficacy due to unique rheology of the cross-linked hydrogel. Injected only once and single injection shows comparable efficacy to a multiple-injection treatment. Obtained marketing authorization as a drug.
	GEM207	A3 adenosine receptor (A3AR) agonist	Rheumatoid arthritis (RA), Psoriasis	Oral	Small molecule	Phase 3	・A3AR is highly expressed in inflammatory and cancer cells. Specific agonists of A3AR induce apoptosis of inflammatory cells but not normal cells. ・Very good safety profile as 1st line therapy. ・In the pahse-2b study (monotherapy vs placebo) for12 weeks in naive RA patients, the endpoint was achieved. ・In the pahse-2/3 study (monotherapy vs placebo) in moderate to severe psoriasis patients, it did not meet the primary endpoint at 12 weeks, but at 32 week the improvement of PASI score was significant vs at 16 week. ・A phase-3 study (vs MTX) in moderate to severe RA and a phase-3 study (vs apremilast) are ongoing.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM059	Recombinant Human Interleukin-1 Receptor Antagonist	Please refer to Note	IM	Protein	Phase 1	Indication: 1: Infection, as manifested by febrile neutropenia, in patients with malignancies receiving chemotherapy drugs. 2: Diarrhea in patients with malignancies receiving chemotherapy drugs. 3. Gout arthritis Note: The world's first multiorgan protection agent for tumor chemotherapy. Inhibits cell cycle progression of normal cells and renders them resistance to chemotherapy. No effects on tumor growth and their sensitivity to chemotherapy Phase 1 : No dose limiting toxicity, None of subjects presented grade 3 or above chemotherapy-induced neutropenia or diarrhea. Gout arthritis: Well tolerated and safe for patients who are restricted from NSAID, glucocorticoid, or colchicine.
	GEM172	Activation of multiple sulfatase	Multiple Sulfatase Deficiency	Oral / or injection	Small molecule	Preclinical – Phase 1 study in preparation	No effective treatment for the rare disease MSD is available. Combination of marketed drugs increase the activity of multiple sulfatases and significantly reduce toxic glycosaminoglycans in MSD fibroblast cell lines. Priority patent, which lead to global application, has been filed. Discussions are available for Japanese companies and Chinese companies
	GEM003	Selective glucocorticoid receptor agonist	RA/OA, Please refer to Note	Local	Small molecule	Preclinical	Updated on January 11, 2019 Expected to reduce unfavorable responses of glucocorticoids by selectivity of action (transrepression>transactivation) Discontinued development for RA/OA. Available for repositioning. Possible indications: Atopic dermatitis, Psoriasis, Asthma, COPD, Inflammatory bowel disease etc.
	GEM040	Topical anti-inflammatory	Joint pain, Muscle pain, Gout, Local inflammatory pain	Topical	Small molecule	Preclinical	Topical formulations of Ibuprofen, Naproxen, Diclofenac to use in the treatment of inflammatory pain and related conditions Formulation shows 5 to 10X increase human skin permeation coupled Potential for OTC or RX introduction: minimal development timeline

Drug candidates by Disease Area

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	GEM061	Curcumin-releasing topical formulation (sustained release for about 24 hours)	Please refer to Note	Topical	Small molecule	Preclinical	Indication: Osteoarthritis, CV disease, chronic inflammatory disease, vascular disease (Sickle Cell) Note: Curcumin's utility: chronic pain, chronic inflammatory conditions such as osteoarthritis, vascular disease such as Sickle Cell and diabetes. This formulation addresses limitations of the poor oral bioavailability of curcumin. Preclinical efficacy demonstrated in an rodent arthritis model and a rodent diabetes model.
	GEM132	Matrix metalloproteinase-13 (MMP-13) inhibitor	Osteoarthritis (OA)	Intraarticular or Oral	Small molecule	Preclinical	Extremely potent non-hydroxamic acid containing, non-zinc binding inhibitors of MMP-13 have been identified. High selectivity has been shown for this class of inhibitors over other MMPs. Lead inhibitor tested in the monoiodoacetate (MIA) rat model of OA and shown to protect cartilage when injected into the joint. Exhibits good oral bioavailability in the rat.
	GEM234	Crosstalk of TGF-β signal and Wnt/β-catenin signal	Liver fibrosis, Nonalcoholic steatohepatitis, Kidney fibrosis, Renal fibrosis, Liver cancer, COVID-19	Injection	Small molecule	Preclinical	GEM234 is a novel small molecular which has suppressive effects on both hepatic stellate cell activation and kidney and liver fibrosis by suppressing TGF-β/Smad pathway via inhibition effect of Wnt/β-catenin pathway. GEM234 shows a higher suppressive effect on liver cancer stem cells than 5-FU. Wnt/β catenin inhibitors can block the infection of SARS-Cov-2, and GEM234 has potential to prevent occurrence of ARDS and cardiovascular damage in COVID-19.
	GEM256	Stem cell repairing	Osteoarthritis	Intra-articular	Peptide	Preclinical	Synthetic novel PEDF-derived short peptide that stimulates cartilage regeneration morphology and pain relief efficacy (MIA-induced model, medial meniscal transection (MMT) model). Long patent protection.Available for licensing globally.
	GEM260	A novel protein that regulates bone metabolizing cells	Osteoporosis	injection	Protein	Preclinical	GEM260 with a novel mechanism for the treatment of bone loss diseases. The GEM260 potently suppresses the induction of osteoclast differentiation and bone resorption, and enhances the expression of osteoblast anabolic factors to promote bone formation in vitro. Evaluation of the therapeutic effect of GEM260 in osteoporosis OVX and calvarial models and inflammatory osteolysis model is currently underway
Otolaryngology	GEM037	Allosteric modulator of the CCR3 receptor	Asthma, Rhinitis	Oral	Small molecule	Phase 2a	In phase 2a: Highly significant effects on the methacholine provocative response Showed trends to improvement in EAR (Early Phase Allergic Response) Reduced induced sputum eosinophil percentage and increased percent blood eosinophil

Drug candidates by Disease Area

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As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM060	Nitric Oxide-releasing topical formulation (sustained release for over 48 hours)	Please refer to Note	Topical	Small molecule	Preclinical	Indication: Acne, Atopic Dermatitis, Fungal diseases, Wound healing, Chronic rhinosinusitis, Diabetic foot ulcers, Raynaud's Phenomenon, Middle-ear infections, Erectile dysfunction, Others Note: NO function: Regulation of the vasculature (vasodilatory), broad spectrum antimicrobial activity, anti-inflammatory, anti-oxidant, wound healing, skin cell maturation and survival etc. Human POC already shown with NO in onychomycosis, genital warts, moscullum contagiosum, pulmonary hypertension, acne, atopic dermatitis (preliminary); animal POC demonstrated in over 20 peer-reviewed papers. Efficacy also demonstrated in preclinical model of erectile dysfunction. This formulation addresses many limitations of NO by providing cost-effective, shelf-stable formulation that provides sustained release of NO.
	GEM249	Antisense oligo nucleotide (ASO) suppressing the expression of human p53 gene	Sensorineural Hearing Loss	Topical	Nucleic acid	Discovery	Suppression of p53 expression may reduce the tissue damage and enhance tissue repair in several disease conditions. It inhibits p53 expression better than the competitor compound in cultured cell, and is therefore expected to be highly effective in clinical practice.
Pain/ Neuropathy	GEM001	TRPV-1 agonist	Rheumatoid arthritis, Please refer to Note	Oral	Small molecule	Phase 2a	Updated on January 11, 2019 Potently inhibits TNF-a production by oral administration. Discontinued development for RA. Available for repositioning. Possible indications: Neuropathic pain, Crohn's disease, Systemic lupus erythematosus, Cachexia, Acute infectious disease, Allergy, Pyrexia, Anemia, Diabetes, Diseases related TNF-α (Colitis, Psoriasis ets.)
	GEM038	Locally acting anti-inflammatory- Trigeminal neuroinflammation	Migraine	Local	Small molecule	Phase 2a	Clinical POC in acute migraine therapy in Phase 2a Efficacy comparable to Triptans but with no systemic side effects or restrictions Shortened development timelines (NDA:2021) Product opportunity for use in Temporomandibular Joint Disease and trigeminal neuralgias
	GEM240	Genetically modified adipocytes	genetic diseases and intractable diseases	Transplant	Gene and Cell therapy	Phase 1	Genetically modified adipocytes for gene therapy and regenerative therapy. It is developed for the treatment of various genetic disease and metabolic disorders. It shows sustainable and stable efficacy or secretion of transduced gene products from implant of GEM240. GEM240 is incomparable and patient-friendly.

Drug candidates by Disease Area

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Accelerating Pharma Licensing

As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM131	Matrix metalloproteinase-2 (MMP-2) and MMP-9 inhibitor	Neuropathic pain and Amyotrophic Lateral Sclerosis (ALS)	Oral	Small molecule	Close to IND ready *	Pain: GEM131 can block inflammatory responses at the site of nerve damage and has been shown to be efficacious in 4 different rodent models of neuropathic pain (spinal nerve ligation, chronic constriction injury of the infraorbital nerve, morphine withdrawal and thermal injury). ALS: Elevated levels of MMP-2 and-9 have been found in the skin and blood of people with ALS. Significantly improved larval locomotion in both the TDP-43 and SOD1 larvae models in Drosophila. Exhibits good oral bioavailability. *: Final stages of completion of IND enabling studies for both neuropathic pain & ALS
	GEM021	Opioid and non-opioid analgesics with respiratory stimulant	Pain	Oral	Small molecule	Preclinical (close to IND)	Combination of generic opioid/non-opioid analgesics with a generic respiratory stimulant using a regulatory approach known as the 505(b)2 submission. First drug introduction therapeutically equivalent to Vicodin® that prevents overdose death, deters abuse and prevents addiction. Low cost of goods.
	GEM002	Kappa-opioid receptor agonist	Pain/Itching, Please refer to Note	Oral	Small molecule	Preclinical	Updated on January 11, 2019 Discontinued development for pain because of company strategy. Available for repositioning. Possible indications: Chronic pains (Back pain, Arthritis pain, Cancer pain, Post-herpetic neuralgia, Trigeminal neuralgia etc.), Pruritus, Irritable bowel syndrome
	GEM040	Topical anti-inflammatory	Joint pain, Muscle pain, Gout, Local inflammatory pain	Topical	Small molecule	Preclinical	Topical formulations of Ibuprofen, Naproxen, Diclofenac to use in the treatment of inflammatory pain and related conditions Formulation shows 5 to 10X increase human skin permeation coupled Potential for OTC or RX introduction: minimal development timeline
	GEM049	Pan-NOX inhibitor	IBD, IPF, Neurodegenerative diseases	Oral	Small molecule	Preclinical	Highly potent NOX inhibitor : 20~50 times more potent than GKT-137831 Significant effects in DNBS-ulcerative colitis and LPS-induced acute inflammatory animal studies. Also showed positive results in IPF animal model. High oral bioavailability and clean off-targets profile
	GEM062	Anandamide(AEA)-releasing topical formulation (sustained release for about 24 hours)	Cutaneous Lupus, (and other autoimmune/ inflammatory skin conditions)	Topical	Small molecule	Preclinical	Tissue imaging to demonstrate efficient penetration and controlled release of AEA from AEA-loaded GEM062. Efficacy of AEA-loaded GEM062 in treating cutaneous lesions in murine model of CLE has been demonstrated.

Drug candidates by Disease Area

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As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM143	CB1, CB2, 5-HT1a	Multiple Sclerosis (MS), Opioid addiction, Chemotherapy induced Peripheral Neuropathic Pain (CIPNP), and Epilepsy	Oral	Small molecule	Preclinical	GEM143 is a nanoencapsulation of the API in biodegradable polymer nanospheres for improved oral bioavailability. MS: The API has multiple actions on key molecular neuroinflammation and neurodegeneration targets, with highly effective in vitro and in vivo bioactivities. Opioid addiction: The API is not an opioid and has been shown to alleviate cue-induced opioid addiction behaviors and allosterically modulate the μ and δ-opioid receptors. CIPNP: Nanoencapsulation is being used to protect the API during the stomach passage. Epilepsy: The API is an effective anti-convulsant with a specificity more comparable to drugs clinically effective in major seizures.
	GEM177	BOTOX Biosimilar	Refer to Note	Injection	Protein	Preclinical	Equivalent efficacy and similar safety profile (for biosimilar for Allergan Botox) Manufacturing using plant-derived mediums Indication - Therapeutic applications: strabismus, cerebral palsy, cervical dystonia, neurogenic bladder, migraine, facial spasm, blepharo spasm - Aesthetic application: all wrinkles produced due to persistent muscular contractions, square jaw reduction, hyperhidrosis
	GEM262	Anti-Inflammatory Drug derived from Resolvin E2	SLE, IBD,RA,Psoriasis, Pain	p.o.	Small molecule	Preclinical	The anti-inflammatory effects of Resolvin E2 are even more potent than clinically effective steroidal and nonsteroidal anti-inflammatory drugs. GEM262 is a new stable compound as an equivalent of Resolvin E2 and promotes the resolution of inflammation by inhibiting neutrophil infiltration and promotion phagocytosis of macrophages in remarkably low doses.
Rare disease	GEM106	Osteoblasts for bone regeneration	Avascular necrosis/Osteonecrosis	Interventional Implantation	Cell therapy	Launch	Live cultured osteoblasts indicated for bone repair and regeneration that stop the progression of avascular necrosis. Over 800 patients were treated with GEM106. Potential label extension to different indications. This product has been granted Orphan Designation by the US FDA & EMA.
	GEM208	A3 adenosine receptor (A3AR) agonist	Liver cancer* NAFLD**	Oral	Small molecule	Phase 3 in preparation* Phase 2 completed**	・A3AR is highly expressed in inflammatory and cancer cells. Specific agonists of A3AR induce apoptosis of cancer cells but not normal cells. ・Very good safety profile. ・An orphan drug status for hepatocellular carcinoma (HCC). ・In phase-2 study in HCC patients, it did not meet the primary endpoint (OS) but subgroup analysis of Child Pugh B patients showed a positive signal of efficacy for OS. ・In phase-2 study (vs placebo) in NAFLD/NASH, it met primary endpoint (liver enzyme) and reduced liver fat, fibrosis and steatosis..

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM096	Progesterone receptor agonist	Recurrent preterm birth	Oral	Small molecule	Phase 2 completed	Potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. An end of Phase 2 meeting was completed with the FDA.
	GEM042	TLR4 antagonist	NAFLD, NASH, AIH, CLD and CD	Oral	Small molecule	Phase 2	NAFLD (nonalcoholic fatty liver disease): The phase 2 results demonstrated significant improvement on relevant diagnosis and biomarkers. NASH: has recently been approved by US FDA for Phase 2 trial (Feb in 2020) AIH (autoimmune hepatitis; orphan designation): The phase 2 (open label) results will be available soon. CLD(chronic liver disease by HCV infection): A strong trend of improvement of liver function and safety in Phase 2. CD (Crohn's disease): Good efficacy in three Phase 2 POC studies. The drug is safe and tolerable in these trials. Can be licensed to territories except Asia
	GEM083	Vasoconstriction and anti-inflammatory action	Hemorrhagic cystitis	Topical (Intravesical)	Small molecule	Phase 2	Pre-liposomal lyophilate containing tacrolimus. POC achieved in animal models of both chemo-cystitis and radiation cystitis. POC achieved in first-in-man experience treating severe recurrent hemorrhagic cystitis. Orphan drug designation granted.
	GEM244	Recombinant human CC10 protein - multiple mechanisms, replacement therapy	Chronic rhinosinusitis* Acute lung injuries**, including Severe acute respiratory infection, Smoke inhalation, ARDS, COPD exacerbation, and Chronic Lung Diseases**, including Bronchiolitis obliterans, Asthma, and COPD	Intranasal, Intravenous and Inhaled	Protein	*Phase 2 (Phase 1 completed) **Phase 1 (Preclinical completed)	GEM244 is a recombinant version of a naturally occurring secretoglobin protein and an unique, clinical-stage, first-in-class biologic for host defense, ARDS, shock, thrombosis, chronic lung diseases, and transplant. - Proof of pharmacology demonstrated in human infants and numerous animal models, for example anti-inflammatory, anti-fibrotic, and disease-modifying activity, allergy, asthma, COPD, lung repair, transplant, burns, shock, and pulmonary edema/pneumonia - Broad spectrum use in respiratory infection such as Influenza, COVID-19, RSV, possibly bacterial pneumonia - Genetic alleles correlate with deficiencies of the native secretoglobin to identify patients most likely to benefit from this therapy as a replacement of the native protein.
	GEM255	Stem cell repairing	Neurotropic keratitis	Topical (eye drop)	Peptide	Phase 1	Synthetic novel neurotrophic PEDF-derived short peptide that stimulates wound healing and corneal repair. Effectively regenerate healthy limbus after extensive limbal layer removal (Rabbit Model) Long patent protection.Available for licensing globally.

Drug candidates by Disease Area

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Accelerating Pharma Licensing

As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM131	Matrix metalloproteinase-2 (MMP-2) and MMP-9 inhibitor	Neuropathic pain and Amyotrophic Lateral Sclerosis (ALS)	Oral	Small molecule	Close to IND ready *	Pain: GEM131 can block inflammatory responses at the site of nerve damage and has been shown to be efficacious in 4 different rodent models of neuropathic pain (spinal nerve ligation, chronic constriction injury of the infraorbital nerve, morphine withdrawal and thermal injury). ALS: Elevated levels of MMP-2 and-9 have been found in the skin and blood of people with ALS. Significantly improved larval locomotion in both the TDP-43 and SOD1 larvae models in Drosophila. Exhibits good oral bioavailability. *: Final stages of completion of IND enabling studies for both neuropathic pain & ALS
	GEM151	anti-GM-CSF monoclonal antibody	Rheumatoid arthritis & multiple new indications* (see note)	i.v.	Antibody	Preclinical (ready for IND-enabling studies)	GM-CSF is a key player in inflammation and autoimmunity. GEM151 is a fully human monoclonal antibody generated by single B cell cloning and has superior affinity (Kd: 7.3 X 10 -11 M) compared to competitors. Neutralizing activities were confirmed by four different functional assays. *cytokine release syndrome., GvHD, multiple sclerosis/neuroinflammation, Kawasaki disease
	GEM172	Activation of multiple sulfatase	Multiple Sulfatase Deficiency	Oral / or injection	Small molecule	Preclinical – Phase 1 study in preparation	No effective treatment for the rare disease MSD is available. Combination of marketed drugs increase the activity of multiple sulfatases and significantly reduce toxic glycosaminoglycans in MSD fibroblast cell lines. Priority patent, which lead to global application, has been filed. Discussions are available for Japanese companies and Chinese companies
	GEM090	Increase cellular ATP and promote wound healing	Epidermolysis bullosa (EB)	Topical	Small molecule	Preclinical	Increasing cellular ATP and speeding up the healing of wounds by promoting the migration of epithelia cells in the skin of wounds. Expected to shorten wound healing time and improve EB patients' QOL with a formulation optimized for EB treatment. Moreover, maybe reduces the risk of squamous cell carcinoma which is highly related to Dystrophic EB patients.
	GEM118	Suppression of TGF-b/Smad and related signaling	Systemic sclerosis	Oral	Small molecule	Preclinical	· Inhibited phosphorylation of Smad3 and expression of Col1a2, FN1 and CTGF stimulated by TGF-b in cultured human dermal fibroblasts. · Ameliorated bleomycin-induced skin fibrosis in both preventative and curative mouse model.

Drug candidates by Disease Area

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As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM143	CB1, CB2, 5-HT1a	Multiple Sclerosis (MS), Opioid addiction, Chemotherapy induced Peripheral Neuropathic Pain (CIPNP), and Epilepsy	Oral	Small molecule	Preclinical	GEM143 is a nanoencapsulation of the API in biodegradable polymer nanospheres for improved oral bioavailability. MS: The API has multiple actions on key molecular neuroinflammation and neurodegeneration targets, with highly effective in vitro and in vivo bioactivities. Opioid addiction: The API is not an opioid and has been shown to alleviate cue-induced opioid addiction behaviors and allosterically modulate the μ and δ-opioid receptors. CIPNP: Nanoencapsulation is being used to protect the API during the stomach passage. Epilepsy: The API is an effective anti-convulsant with a specificity more comparable to drugs clinically effective in major seizures.
	GEM262	Anti-Inflammatory Drug derived from Resolvin E2	SLE, IBD,RA,Psoriasis, Pain	p.o.	Small molecule	Preclinical	The anti-inflammatory effects of Resolvin E2 are even more potent than clinically effective steroidal and nonsteroidal anti-inflammatory drugs. GEM262 is a new stable compound as an equivalent of Resolvin E2 and promotes the resolution of inflammation by inhibiting neutrophil infiltration and promotion phagocytosis of macrophages in remarkably low doses.
	GEM248	Antisense oligo nucleotide (ASO) suppressing the expression of human p53 gene	ALS(C9orf72)	Intramedullary	Nucleic acid	Discovery	Suppression of p53 expression may reduce the tissue damage and enhance tissue repair in several disease conditions. It inhibits p53 expression better than the competitor compound in cultured cell, and is therefore expected to be highly effective in clinical practice.
Regenerative medicine	GEM106	Osteoblasts for bone regeneration	Avascular necrosis/Osteonecrosis	Interventional Implantation	Cell therapy	Launch	Live cultured osteoblasts indicated for bone repair and regeneration that stop the progression of avascular necrosis. Over 800 patients were treated with GEM106. Potential label extension to different indications. This product has been granted Orphan Designation by the US FDA & EMA.
	GEM107	Chondrocytes for hyaline cartilage regeneration.	Articular cartilage defects	Interventional Implantation	Cell therapy	Launch	Live cultured chondrocytes indicated for hyaline cartilage regeneration in cartilage injuries. Over 700 patients treated with several publications and patent protection.
	GEM237	Autologous chondrocyte cell therapy for cartilage repair/regeneration	Chondral and osteochondral articular lesions of the knee	Arthroscopic implantation	Cell and scaffold	Launch	The autologous cartilage repair system (a device kit consisting of a bioabsorbable highly porous scaffold and an enzyme for processing removed a small amount of cartilage) is for one-step surgery. It does not require an *ex vivo* cell expansion process. Hyaline cartilage is regenerated and long-term effectiveness is superior to the marrow stimulation procedure.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM036	Hematopoietic stem cell fucosylation	Prevention of infection & GvHD from hematopoietic stem cell transplantation	Infusion	Protein	Phase 3 ready with FDA SPA	In Phase 2 study: Statistically significant acceleration of immune system reconstitution (neutrophil/platelet recovery) Significantly reduced infection and GvHD Improved survival Positioned to be best-in-class No reports of adverse event specifically attributable to fucosylation
	GEM108	Buccal Epithelial cells for re-epithelization	Urethral strictures	Implantation	Cell therapy	Phase 2b completed	Live cultured buccal epithelial cells indicated for urethral strictures. Excellent safety and efficacy profiles have been established through Phase 2b clinical trials. Potential label extension to rare disease in pediatric population; hypospadias.
	GEM187	Mesenchymal stem cell	Rheumatoid Arthritis (RA), Inflammatory Bowel Disease (IBD), COVID-19	Implant (allogenic)	Cell	IND	GEM187 is a fresh (non-frozen) human allogenic umbilical cord tissue derived mesenchymal stem cells (hUC-MSC) product. - Proprietary manufacturing process with no risk of contamination. - “Youngest” adult MSC with robust proliferation capacity. - Highly scalable to achieve enough cells. - Superior biological functions: optimal cell viability and biological functions maintained for therapeutic use.
	GEM141	Esophageal implant (See note)	Pediatric esophageal atresia and other conditions that affect the esophagus	Implant (autologous)	Cell therapy	IND ready	Esophageal implant made by combining a novel cell therapy platform (see TGEM38) with a patient’s own cells (hematopoietic stem and precursor cells). GEM141 leverages the body’s inherent capacity to heal itself as it is a “living tube” that facilitates regeneration of esophageal tissue and triggers a positive host response resulting in a tissue-engineered neo-conduit that restores continuity of the esophagus. These implants have the potential to dramatically improve the quality of life for children and adults
Renal disease	GEM182	Direct renin inhibitor (DRI)	Hypertension (HP), diabetic nephropathy (DKD), chronic hemodialysis, heart failure	Oral	Small molecule	HP : Phase 2 ready DKD: Phase 2 completion	A 2nd generation DRI with better renoprotective effects than ACEi/ARB. Better hypotensive effects than aliskiren is expected due to higher BA, less variability and no food effect following oral treatment. Prolonged renal localization, blood pressure independent renoprotection and positive effect on renal blood flow are evidenced by DRIs. In clinical trials of GEM182 in T2DM patients with microalbuminuria, dose-dependent UACR reduction and increases in remission rate from albuminuria were also seen. This compound have been developed as mono-therapy (not combined with ACEi/ARB). Therefore, GEM182 has no safety issues seen in aliskiren's ALTITUDE trial due to RAS dual blockade. Injectable formulation is also developed (ref. GEM183). Licensing discussion is available except for China.

Drug candidates by Disease Area

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As of 01/14/22

Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM265	Enteropeptidase inhibitor	Kidney diseases, Diabetes	Oral	Small molecule	Phase 2	1) GEM265 is an orally bioactive enteropeptidase inhibitor with a first-in-class potential. 2) GEM265 showed therapeutic efficacy in pre-clinical disease models with kidney diseases and diabetes. 3) Phase 1 and Phase 2a studies were completed. - Good safety and tolerability were confirmed (up to 1500 mg/day was safe and well tolerated for 12 weeks). - GEM265-induced biomarker change (plasma amino acid changes) was confirmed. - GEM265 treatment for 12 weeks resulted in a significant reduction on urine albumin-to-creatinine ratio (UACR) from baseline in patients with diabetic kidney disease (DKD) treated with anti-hyperglycemic agents as well as renin-angiotensin system inhibitors. GEM265 also decreased HbA1c levels in DKD patients.
	GEM223	IP6K inhibitor (Inhibition of cellular phosphate export and regulation of intracellular energy status)	Cancer chemotherapy-associated hyperphosphatemia, Chronic kidney disease-associated hyperphosphatemia	Oral Intravenous	Small molecule	Pre-IND	1) Originator identified a new MOA that IP6K inhibition as a new mechanism in lowering circulating phosphate - IP6K has a physiological role in regulating circulating phosphate and intracellular ATP levels - GEM223 is an in vivo effective IP6K inhibitor with a first-in-class potential - A robust therapeutic effect in improving hyperphosphatemia and ameliorating organ function were observed in preclinical settings - Four-week toxicological studies were completed in rats and monkeys
	GEM183	Direct renin inhibitor (DRI)	Blood pressure control and/or prevention of heart failure in patients with chronic hemodialysis	i.v.	Small molecule	Preclinical	Injectable formulation of GEM182 (oral formulation in phase-2b), is also being developed for potential use for better blood pressure control and/or prevention of heart failure by chronic intravenous treatment three times per week via vascular access established in patients with chronic hemodialysis. Renin inhibitor may be suitable for such patients who often exhibit hyperreninemia potentially due to residual function of juxtaglomerular apparatus as well as reduced renal blood flow after start of the hemodialysis. Although dialysis patients are mostly unavoidable from hypertension, no optimal treatment has been available yet. GEM183 can fulfill such rapid growing huge unmet medical needs. Licensing discussion is available except for China.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM234	Crosstalk of TGF-β signal and Wnt/β-catenin signal	Liver fibrosis, Nonalcoholic steatohepatitis, Kidney fibrosis, Renal fibrosis, Liver cancer, COVID-19	Injection	Small molecule	Preclinical	GEM234 is a novel small molecular which has suppressive effects on both hepatic stellate cell activation and kidney and liver fibrosis by suppressing TGF-β/Smad pathway via inhibition effect of Wnt/β-catenin pathway. GEM234 shows a higher suppressive effect on liver cancer stem cells than 5-FU. Wnt/β catenin inhibitors can block the infection of SARS-Cov-2, and GEM234 has potential to prevent occurrence of ARDS and cardiovascular damage in COVID-19.
	GEM245	Recombinant protein based on complement inhibitor C4BP with anti-inflammatory and tolerogenic action	Autoimmune diseases including SLE, IBD and RA	s.c. injection	Protein	Preclinical (before GLP)	・Recombinant protein based on endogenous complement inhibitor C4BP exerts anti-inflammatory and tolerogenic action on dendritic cells. ・A novel biologic for immunomodulation, not immunosuppression. ・Reduces TLR-induced overproduction of proinflammatory cytokines (IL-12, TNF-alpha, IFN-gamma). ・Confirmed in vivo efficacy in SLE model, RA model, and DSS-induced colitis model. ・Global IP coverage (incl. compositions)
	GEM251	Antisense oligo nucleotide (ASO) suppressing the expression of human p53 gene	AKI(acute kidney injury), Heart failure, Stroke	i.v.	Nucleic acid	Discovery/ Preclinical	Suppression of p53 expression may reduce the tissue damage and enhance tissue repair in several disease conditions. It inhibits p53 expression better than the competitor compound in cultured cell, and is therefore expected to be highly effective in clinical practice.
	GEM171	ARNT regulation	Fibrosis in kidney, heart and liver	Oral / or gene therapy	Small molecule or morpho-linos	Discovery – Preclinical	No effective therapy for fibrosis is available yet. ARNT homodimerizartion attenuates fibrosis progression and induces regenerative cellular responses. Several mechanisms of action and potential drugs were identified, which show inhibition of ARNT degradation or activation of ARNT expression. PCT patent application filed. Discussions are available for Japanese companies and Chinese companies.
Respiratory	GEM-CVD05	Immune-modulate and slow down the hyperactive active immune system from attacking lung cells (and other solid organs)	Prevention of Respiratory Failure by Treating Acute Respiratory Disease Syndrome Resulting from COVID-19 and other viral pandemics	Refer to Note*	Protein**	Phase 3 ready***	1. Treatment of blood/MSCs, Tregs, NK cells with GEM-CVD05 to improve their homing to patients' lungs, thereby enabling those cells to slow down the hyperactive immune attack on the lungs to help prevent deaths from respiratory failure. 2. Treatment of cells such as stem cells enabling them to home/engraft more effectively to the bone marrow and accelerating immune reconstitution with 'younger' immune cells for improved viral infected cell killing. *Infusion with blood, or MSCs, Tregs, NK cells to improve efficacy, safety and cost of care outcomes **Used to treat MSCs, Blood, Tregs, NK cells , Stem Cells to Prevent deaths from respiratory failure ***Phase 2 study for other indication has been completed.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM037	Allosteric modulator of the CCR3 receptor	Asthma, Rhinitis	Oral	Small molecule	Phase 2a	In phase 2a: Highly significant effects on the methacholine provocative response Showed trends to improvement in EAR (Early Phase Allergic Response) Reduced induced sputum eosinophil percentage and increased percent blood eosinophil
	GEM243	Known and available under CDA	Mucositis Prevention and Treatment, Fibrotic Disease Treatment	Injectable or Oral	Small molecule	Phase 2	Small molecule drug for the prevention and treatment of chemotherapy and radiation therapy induced mucositis. Also shows activity intreating fibrotic diseases such as pulmonary fibrosis and NASH. GEM243 has successfully completed POC human clinical studies in head and neck cancer patients for chemotherapy-induced mucositis prevention with excellent results. GEM243 has shown to be extremely safe and highly effective in P1a, P1b, and P2a human clinical studies. Potentially useful in preventing and treating chemotherapy-induced pulmonary fibrosis and as a direct treatment for diseases such as Covid-19-induced pulmonary fibrosis, idiopathic pulmonary fibrosis, and NASH.
	GEM244	Recombinant human CC10 protein - multiple mechanisms, replacement therapy	Chronic rhinosinusitis* Acute lung injuries**, including Severe acute respiratory infection, Smoke inhalation, ARDS, COPD exacerbation, and Chronic Lung Diseases**, including Bronchiolitis obliterans, Asthma, and COPD	Intranasal, Intravenous and Inhaled	Protein	*Phase 2 (Phase 1 completed) **Phase 1 (Preclinical completed)	GEM244 is a recombinant version of a naturally occurring secretoglobin protein and an unique, clinical-stage, first-in-class biologic for host defense, ARDS, shock, thrombosis, chronic lung diseases, and transplant. - Proof of pharmacology demonstrated in human infants and numerous animal models, for example anti-inflammatory, anti-fibrotic, and disease-modifying activity, allergy, asthma, COPD, lung repair, transplant, burns, shock, and pulmonary edema/pneumonia - Broad spectrum use in respiratory infection such as Influenza, COVID-19, RSV, possibly bacterial pneumonia - Genetic alleles correlate with deficiencies of the native secretoglobin to identify patients most likely to benefit from this therapy as a replacement of the native protein.
	GEM073	Kinase inhibitor of TGFβ-mediated phospho-SMAD2 signal transduction	COPD, IPF, Lung cancer	Oral	Small molecule	Phase 1	This kinase is selectively expressed in resident macrophages and airways epithelia of the lung and upregulated in COPD and IPF patients. A highly selective inhibitor showed efficacy across at least 3 different animal models relevant to COPD, IPF and NSCLC. Phase 1 trial has completed with a clean safety and tolerability profile

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM035	An anti-ENO1 antibody	Immune diseases, Various cancers	s.c.	Protein	US FDA IND cleared	GEM035 is a humanized antibody against unique ENO1 target. This therapeutic antibody is first-in-class to target inflammatory macrophage and demonstrates efficacy in animal models of MS, IPF, and IBD. It also showed efficacy in animal models of lung, pancreatic, and prostate cancer, most likely by targeting tumor associated macrophage (TAM). GEM035 may be developed for treatment of COVID-19 induced ARDS based on its capability to suppress macrophage related immune response. GEM035 has a worldwide patent protection. US IND of GEM035 is approved and active now for treating MS.
	GEM003	Selective glucocorticoid receptor agonist	RA/OA, Please refer to Note	Local	Small molecule	Preclinical	Updated on January 11, 2019 Expected to reduce unfavorable responses of glucocorticoids by selectivity of action (transrepression>transactivation) Discontinued development for RA/OA. Available for repositioning. Possible indications: Atopic dermatitis, Psoriasis, Asthma, COPD, Inflammatory bowel disease etc.
	GEM049	Pan-NOX inhibitor	IBD, IPF, Neurodegenerative diseases	Oral	Small molecule	Preclinical	Highly potent NOX inhibitor : 20~50 times more potent than GKT-137831 Significant effects in DNBS-ulcerative colitis and LPS-induced acute inflammatory animal studies. Also showed positive results in IPF animal model. High oral bioavailability and clean off-targets profile
	GEM234	Crosstalk of TGF-β signal and Wnt/β-catenin signal	Liver fibrosis, Nonalcoholic steatohepatitis, Kidney fibrosis, Renal fibrosis, Liver cancer, COVID-19	Injection	Small molecule	Preclinical	GEM234 is a novel small molecular which has suppressive effects on both hepatic stellate cell activation and kidney and liver fibrosis by suppressing TGF-β/Smad pathway via inhibition effect of Wnt/β-catenin pathway. GEM234 shows a higher suppressive effect on liver cancer stem cells than 5-FU. Wnt/β catenin inhibitors can block the infection of SARS-Cov-2, and GEM234 has potential to prevent occurrence of ARDS and cardiovascular damage in COVID-19.
	GEM246	Anti-SARS-Cov-2 IgY antibody	COVID-19	Intra-nasal or inhalation	Antibody	Preclinical	・IgY antibody extracted from egg yolk of hens immunized with SARS-Cov-2 virus. ・The highest concentration of antibodies in the animal kingdom is found in a single egg yolk ・Faster and lower cost in manufacturing vs monoclonal antibody ・Could be used for both therapeutic and prophylactic purposes (passive immunization) ・Looking for partners in Japan and South Korea.

Drug candidates by Disease Area

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
Rheumatology	GEM207	A3 adenosine receptor (A3AR) agonist	Rheumatoid arthritis (RA), Psoriasis	Oral	Small molecule	Phase 3	・A3AR is highly expressed in inflammatory and cancer cells. Specific agonists of A3AR induce apoptosis of inflammatory cells but not normal cells. ・Very good safety profile as 1st line therapy. ・In the pahse-2b study (monotherapy vs placebo) for12 weeks in naive RA patients, the endpoint was achieved. ・In the pahse-2/3 study (monotherapy vs placebo) in moderate to severe psoriasis patients, it did not meet the primary endpoint at 12 weeks, but at 32 week the improvement of PASI score was significant vs at 16 week. ・A phase-3 study (vs MTX) in moderate to severe RA and a phase-3 study (vs apremilast) are ongoing.
	GEM001	TRPV-1 agonist	Rheumatoid arthritis, Please refer to Note	Oral	Small molecule	Phase 2a	Updated on January 11, 2019 Potently inhibits TNF-a production by oral administration. Discontinued development for RA. Available for repositioning. Possible indications: Neuropathic pain, Crohn's disease, Systemic lupus erythematosus, Cachexia, Acute infectious disease, Allergy, Pyrexia, Anemia, Diabetes, Diseases related TNF-α (Colitis, Psoriasis ets.)
	GEM155	FPR2-specific ligand	Atopic dermatitis/Psoriasis, Dry eye disease, IBD (Inflammatory bowel disease), Asthma, Rheumatoid arthritis	Topical, Eye drop, s.c.	Peptide	Phase 1	GEM155 is a small (7mer) lipidated peptide ligand for pro-resolving receptor FPR2 (N-formyl peptide receptor 2) involved in regulation of innate immune system and inhibition of ILC2 function (adaptive immune system). It also has anti-microbial effect for pathogenic bacteria through fusion with functional moiety. Efficacy is seen in animal models for the indications. CMC study is almost done. Toxicity study for topical usage and subcutaneous injection is going-on. Formulation for topical use is almost finished.
	GEM187	Mesenchymal stem cell	Rheumatoid Arthritis (RA), Inflammatory Bowel Disease (IBD), COVID-19	Implant (allogenic)	Cell	IND	GEM187 is a fresh (non-frozen) human allogenic umbilical cord tissue derived mesenchymal stem cells (hUC-MSC) product. - Proprietary manufacturing process with no risk of contamination. - "Youngest" adult MSC with robust proliferation capacity. - Highly scalable to achieve enough cells. - Superior biological functions: optimal cell viability and biological functions maintained for therapeutic use.
	GEM151	anti-GM-CSF monoclonal antibody	Rheumatoid arthritis & multiple new indications* (see note)	i.v.	Antibody	Preclinical (ready for IND-enabling studies)	GM-CSF is a key player in inflammation and autoimmunity. GEM151 is a fully human monoclonal antibody generated by single B cell cloning and has superior affinity (Kd: 7.3 X 10 -11 M) compared to competitors. Neutralizing activities were confirmed by four different functional assays. *cytokine release syndrome., GvHD, multiple sclerosis/neuroinflammation, Kawasaki disease

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	GEM003	Selective glucocorticoid receptor agonist	RA/OA, Please refer to Note	Local	Small molecule	Preclinical	Updated on January 11, 2019 Expected to reduce unfavorable responses of glucocorticoids by selectivity of action (transrepression>transactivation) Discontinued development for RA/OA. Available for repositioning. Possible indications: Atopic dermatitis, Psoriasis, Asthma, COPD, Inflammatory bowel disease etc.
	GEM009	BET inhibitor	Cancer, RA	Oral	Small molecule	Preclinical	Updated on January 11, 2019 More potent enzyme inhibition and anti-tumor activities compared with competitors (more potent than GSK525762A and comparable to ABBV-075). Superior safety profile than competitors (no inhibition on hERG or CYP3A4) and can be applied to RA. Easier manufacturing due to absence of asymmetric carbon.
	GEM138	Biosimilar adalimumab	Same indications as adalimumab	i.v.	Antibody	Preclinical	Purified GEM138 is highly similar to adalimumab by SDS-PAGE. GEM138 and adalimumab show a similar response in a TNF-a ELISA assay. Plant-based technology (TGEM036) was applied for production of GEM138.
	GEM245	Recombinant protein based on complement inhibitor C4BP with anti-inflammatory and tolerogenic action	Autoimmune diseases including SLE, IBD and RA	s.c. injection	Protein	Preclinical (before GLP)	・Recombinant protein based on endogenous complement inhibitor C4BP exerts anti-inflammatory and tolerogenic action on dendritic cells. ・A novel biologic for immunomodulation, not immunosuppression. ・Reduces TLR-induced overproduction of proinflammatory cytokines (IL-12, TNF-alpha, IFN-gamma). ・Confirmed in vivo efficacy in SLE model, RA model, and DSS-induced colitis model. ・Global IP coverage (incl. compositions)
Urology	GEM092	Androgen receptor agonist	Hypogonadism	Oral (BID)	Small molecule	Received FDA tentative approval	A novel oral prodrug of testosterone that is designed to help restore normal testosterone levels in hypogonadal men. GEM092 was well tolerated and met the primary end-points in Phase 3 testing with twice daily dosing. Easy to use for patients and physicians to prescribe due to fixed doing regimen.
	GEM088	SSRI with agonist-antagonistic action on 5-HT receptors	Urinary incontinence	Oral	Small molecule	Phase 3 ready	Repositioning from another indication and has already a proven record of good safety in more than 300 patients with further 300 treated in phase 2. It has shown therapeutic activity in animal models of both stress and urge urinary incontinence. In phase 2 trials, clinically meaningful effects in mixed incontinence were shown as well as very good tolerability. The compound is ready to enter phase 3.

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	GEM093	Androgen receptor agonist	Hypogonadism	Oral (QD)	Small molecule	Phase 2 completed	A novel next generation oral prodrug of testosterone with potential for once-daily oral dosing that has completed Phase 2 testing.
	GEM108	Buccal Epithelial cells for re-epithelization	Urethral strictures	Implantation	Cell therapy	Phase 2b completed	Live cultured buccal epithelial cells indicated for urethral strictures. Excellent safety and efficacy profiles have been established through Phase IIb clinical trials. Potential label extension to rare disease in pediatric population; hypospadias.
	GEM083	Vasoconstriction and anti-inflammatory action	Hemorrhagic cystitis	Topical (Intravesical)	Small molecule	Phase 2	Pre-liposomal lyophilate containing tacrolimus. POC achieved in animal models of both chemo-cystitis and radiation cystitis. POC achieved in first-in-man experience treating severe recurrent hemorrhagic cystitis. Orphan drug designation granted.
	GEM129	Immuno-modulator	Anogenital warts, Actinic keratosis, Basal cell carcinoma	Topical	Small molecule	Phase 2	· The first product on the market that combines the therapeutic benefits of a marketed immunomodulator with an innovative transparent bioadhesive film. · When applied to the lesion, generates a transparent bioadhesive film, which acts as a reservoir or matrix release and reduces the local reactions and increases the permanence of the product in the action site. · The results of non-clinical studies demonstrate that GEM129 has a better safety profile with an equivalent efficacy than its reference product. Clinical studies on-going.
	GEM060	Nitric Oxide-releasing topical formulation (sustained release for over 48 hours)	Please refer to Note	Topical	Small molecule	Preclinical	Indication: Acne, Atopic Dermatitis, Fungal diseases, Wound healing, Chronic rhinosinusitis, Diabetic foot ulcers, Raynaud's Phenomenon, Middle-ear infections, Erectile dysfunction, Others Note: NO function: Regulation of the vasculature (vasodilatory), broad spectrum antimicrobial activity, anti-inflammatory, anti-oxidant, wound healing, skin cell maturation and survival etc. Human POC already shown with NO in onychomycosis, genital warts, moscullum contagiosum, pulmonary hypertension, acne, atopic dermatitis (preliminary); animal POC demonstrated in over 20 peer-reviewed papers. Efficacy also demonstrated in preclinical model of erectile dysfunction. This formulation addresses many limitations of NO by providing cost-effective, shelf-stable formulation that provides sustained release of NO.

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	GEM177	BOTOX Biosimilar	Refer to Note	Injection	Protein	Preclinical	Equivalent efficacy and similar safety profile (for biosimilar for Allergan Botox) Manufacturing using plant-derived mediums Indication - Therapeutic applications: strabismus, cerebral palsy, cervical dystonia, neurogenic bladder, migraine, facial spasm, blepharo spasm - Aesthetic application: all wrinkles produced due to persistent muscular contractions, square jaw reduction, hyperhidrosis
	GEM209	A3 adenosine receptor (A3AR) allosteric modulator	Erectile dysfunction	Oral	Small molecule	Preclinical	・Specific agonists of A3AR induce modulation of key signaling proteins, such as PI3K, GSK-3β, PKA, PKB/Akt, IKK, and NF-κB, and show anti-inflammatory effects. ・Very good safety profile. ・GEM209 increased eNOS and VEGF in the cavernosal endothelial cells. ・A single dose showed a full recovery in function of in an erectile dysfunction rat model.
Vaccine	GEM-CVD01	SARS-CoV-2 spike protein expression from RNA followed by antibody response	COVID-19	Intramuscular	RNA Vaccine	Phase 1	This program is a rapid COVID-19 vaccine development. This vaccine is developed on the basis of established technologies of RNA delivery and nanostructured lipid carrier formulation. GEM-CVD01 rapidly induces robust immune responses.
	GEM-CVD03	Fast response oral vaccine	COVID-19	Oral	Vaccine	Phase-1/2	First-in-class COVID-19 immunotherapy to be used as an oral vaccine. This company has a track record to manufacture oral vaccine against highly pathogenic avian flu virus H5N1 on one week time. Oral vaccine will be easier to distribute to a large number of potentially virus-exposed people within very short period of time. The company is looking for partner who make the company accessing the virus and finance to manufacture the first batch within one week.
	GEM168	Heat-killed mycobacterium vaccae	Tuberculosis (TB)	Oral	Vaccine	Phase 3	First-in-class tuberculosis immunotherapy to be used as an oral adjunct to standard TB drugs. In a 1-month phase 2 trial, the mycobacterial clearance in sputum smears was observed in 72% and 19% of patients on GEM168 and placebo, respectively.
	GEM069	Immuno-modulator (adjuvant)	Vaccine, Cancer immunotherapy etc.	Injection	Other	Preclinical	*E.coli* producing monophosphoryl Lipid A whose structure is similar to existing adjuvants such as MPL and GLA. Shows similar efficacy with MPL in vitro and in vivo. Lower cost production through simple fermentation and purification steps
	GEM139	*Staphylococcus aureus* vaccine	*Staphylococcus aureus* infection	s.c.	Vaccine	Preclinical	The vaccine comprising antigens and toxin is being developed. The candidate antigens to block the immune-evasion pathway by MSCRAMMs and toxin of *S. aureus* have already been defined.

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	GEM201	mRNA Vaccine Platform technology. Production of S-Protein with Immune-modulators in one construct.	Coronavirus (COVID-19); Broader Vaccine Platform	i.v.	Drug Delivery, Cell therapy	Preclinical	GEM201 utilizes TGEM055 technology loaded with antigenetic proteins as a mRNA Vaccine Platform - Produce functional antigenetic proteins in Lymphatic organs - Localized antigen induction at high intracellular amounts where antigen presenting cells aggregate. Co-delivery of potent Immune-modulators (GM-CSF, IL-12, etc.) simultaneously - GEM201 is a vaccine platform - GEM201 is critical for vaccination of elderly and immune suppressed population
	GEM075	Novel functional excipient	Oral formulation (e.g. Direct compression, Granulation, Solid dispersion)	Oral	Polymer	Preclinical	The synthetic polyvinyl acetate (PVAc)-based polymer of functional excipient is utilized as solubilizer that could increase drug solubility and enhance drug absorption. This novel excipient has better flowability, easy for use and widely application. This excipient will be useful for new drug and insoluble drug development.
Others	GEM128	Antibiotic	Primary and secondary skin infection - canine pyoderma	Topical	Small molecule	Clinical for animal	· The first medicine on the market that combines the therapeutic benefits of a marketed antibiotic with an innovative film-forming, long-lasting delivery technology. · When applied to the lesion, generates a transparent film that acts as a bioadhesive sustained release matrix maintaining the optimum concentration of the antibiotic in the skin for a period of 6-8 hours. · The bioadhesive film generated reduces product removal from the area due to animal scratching, licking or friction with skin folds which contribute in improving the treatment efficacy. Also, reduces oral antibiotic overusing by improving topical treatment with this innovative technology. *Canine bacterial infections of the skin, including superficial pyoderma
	GEM153	Angiogenic peptide	Wound-care, Diabetic foot ulcer, Cosmetics	Topical	Peptide	Preclinical	Increases blood vessel formation (VEGFA/VEGFR1 expression ↑& cell proliferation/migration ↑). Boosts collagen synthesis at sub-nanomolar concentration (Wrinkle-care) & inhibits melanin synthesis (Whitening). Registered cosmetic ingredient.
	GEM154	Collagen-inducing peptide	Dermal filler, Cosmetics	Topical	Peptide	Preclinical	Laminin-derived peptide. Boosts collagen synthesis at sub-nanomolar concentration (Wrinkle-care) & inhibits melanin synthesis (Whitening). Registered cosmetic ingredient.
	GEM177	BOTOX Biosimilar	Refer to Note	Injection	Protein	Preclinical	Equivalent efficacy and similar safety profile (for biosimilar for Allergan Botox) Manufacturing using plant-derived mediums Indication - Therapeutic applications: strabismus, cerebral palsy, cervical dystonia, neurogenic bladder, migraine, facial spasm, blepharo spasm - Aesthetic application: all wrinkles produced due to persistent muscular contractions, square jaw reduction, hyperhidrosis

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Disease area	Candidate	Mode of action	Indication	Route	Modality	Development stage	Note
	GEM162	Restoration of autophagy and reduction of inflammation	Age-related diseases**	Oral	Oligo-saccharides	NDIN** ready	A novel, intestinally absorbable derivative (pat. pend.) of GRAS αCD (α-cyclodextrin) as an intermittent fasting mimetic. βCDs have been effective in vivo against many age-related diseases, including cancer, AD, and PD. αCDs are more effective against endocytosis than βCDs and lack the βCDs' ototoxicity. In the EU, oral αCD may claim to "reduce post-prandial glycemic response", but has low and variable bioavailability. **New dietary ingredient notification as a nutritional supplement/FSMP
	GEM162	Restoration of autophagy and reduction of inflammation	Age-related diseases**	Oral	Oligo-saccharides	NDIN** ready	A novel, intestinally absorbable derivative (pat. pend.) of GRAS αCD (α-cyclodextrin) as an intermittent fasting mimetic. βCDs have been effective in vivo against many age-related diseases, including cancer, AD, and PD. αCDs are more effective against endocytosis than βCDs and lack the βCDs' ototoxicity. In the EU, oral αCD may claim to "reduce post-prandial glycemic response", but has low and variable bioavailability. **New dietary ingredient notification as a nutritional supplement/FSMP
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	GEM162	Restoration of autophagy and reduction of inflammation	Age-related diseases**	Oral	Oligo-saccharides	NDIN** ready	A novel, intestinally absorbable derivative (pat. pend.) of GRAS αCD (α-cyclodextrin) as an intermittent fasting mimetic. βCDs have been effective in vivo against many age-related diseases, including cancer, AD, and PD. αCDs are more effective against endocytosis than βCDs and lack the βCDs' ototoxicity. In the EU, oral αCD may claim to "reduce post-prandial glycemic response", but has low and variable bioavailability. **New dietary ingredient notification as a nutritional supplement/FSMP
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