10. Pipeline (as of January 30, 2026)

Areas	Generic name/Code No. [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Infectious disease	Cefiderocol Tosilate Sulfate Hydrate [US, Japan: Fetroja®] [EU:Fetcroja®]	Cell-wall synthesis inhibition (injection)	Gram-negative infection (pediatric)	Phase III	In-house	In-house
			Gram-negative infection	Phase III Approval: China (Jan. 2026) MAA submission: Australia (Dec. 2024)	In-house	In-house
	Baloxavir marboxil [USA:Xofluza™] [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection (body weight <20kg)	Approval: Japan (Sep. 2025)	In-house	In-house/ Roche (Switzerland)
	S-268019 [Japan:Covgoze®]	Vaccine (muscular injection)	Prevention of COVID-19 (Adolescent)	Phase II/III	In-house	In-house
			Prevention of COVID-19 (Children)	Phase I/II/III	In-house	In-house
	S-268024	Vaccine (muscular injection)	Prevention of COVID-19	NDA submission: Japan (Nov. 2025)	In-house	In-house
	S-567123	Vaccine (muscular injection)	Prevention of COVID-19	Phase I	In-house	In-house
	Ensitrelvir Fumaric Acid [Japan:Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19 (12 years old and older)	Phase III NDA submission: EU (Jun. 2025)	In-house	Japan, global, Taiwan: In-house South Korea: In-house/Ildong Singapore: In-house/Juniper
			Treatment of COVID-19 (Children, 6 to 11 years)	NDA submission: Japan (Jun. 2025)	In-house	In-house
			Post exposure prophylaxis of COVID-19	NDA submission: Japan (Mar. 2025) , US (Jun. 2025) , EU (Jun. 2025) Taiwan (oct. 2025)	In-house	In-house
			Treatment of COVID-19 (Pediatric, 0 to 5 years)	Phase Ⅲ	In-house	In-house
	Olorofim	Dihydroorotate dehydrogenase (DHODH) inhibition (oral)	Invasive aspergillosis	Phase III	F2G (UK)	In-house/ F2G
	S-892216	3CL protease inhibitor (oral)	Treatment of COVID-19	Phase II	In-house	In-house
		3CL protease inhibitor (long-acting injection)	Pre exposure prophylaxis of COVID-19	Phase I	In-house	In-house
	S-337395	RNA dependent RNA polymerase inhibitor (oral)	Treatment of RSV infection	Phase II	In-house/ UBE	In-house/ UBE
	S-743229	Cell-wall synthesis inhibition (oral)	Complicated urinary tract infections, including pyelonephritis	Phase I	In-house/ Qpex	In-house
	S-649228	Cell-wall synthesis inhibition (injection)	Gram-negative infection	Phase I	In-house/ Qpex	In-house
QOL Diseases	Naldemedine tosilate [Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, powder)	Opioid-induced constipation (pediatric)	Phase I/II	In-house	In-house
		Peripheral opioid receptor antagonist (oral)	Opioid-induced constipation	Phase III NDA submission: China (May. 2025)	In-house	In-house
	Zuranolone	$GABA_A$ receptor positive allosteric modulator (oral)	Depression	Approval: Japan (Dec. 2025)	Supernus (USA)	In-house/ Supernus
	SDT-001 [Japan:ENDEAVORRIDE®]	Treatment digital application based on cerebral mechanism	Treatment of ADHD (pediatric)	Approval: Japan (Feb. 2025)	Akili (USA)	In-house/ Akili
	Zatolmilast	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	Phase II/III	Tetra (USA)	In-house
			Jordan syndrome	Phase II	Tetra (USA)	In-house
			Alzheimer's disease	Phase II	Tetra (USA)	In-house
	Resiniferatoxin	TRPV1 agonist (Intra-articular injection)	Pain associated with osteoarthritis of knee	Phase III	Grünenthal (Germany)	Grünenthal
	S-151128	Nav1.7 inhibitor (injection)	Chronic pain	Phase I	In-house	In-house
	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Phase I/II	Rohto (Japan)	In-house/ Rohto
	S-309309	Monoacylglycerol acyltransferase 2 inhibitor (oral)	Obesity	Phase II	In-house	In-house
	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Phase III	OncoTherapy Science, Inc.(Japan)	In-house
			Bladder cancer	Phase II	OncoTherapy Science, Inc.(Japan)	In-house
	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Phase I/II	OncoTherapy Science, Inc.(Japan)	In-house

Areas	Generic name/Code No. [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
QOL Diseases	S-588210	Cancer peptide vaccine (injection)	Solid tumor	Phase I	OncoTherapy Science, Inc. (Japan)	In-house
	S-222611 (Epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Phase I/II	In-house	In-house
	SR-0379	Promote granulation formation (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Phase III	FunPep (Japan)	In-house/ FunPep
	Redasemtide Trifluoroacetate	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Phase IIb	StemRIM (Japan)	In-house
			Epidermolysis bullosa	Phase II	StemRIM (Japan)	In-house
	S-531011	anti-CCR8 antibody (injection)	Solid tumor	Phase Ib/II	In-house	In-house
	S-740792	New mechanism of action (oral)	Walking impairment associated with multiple sclerosis	Phase I	In-house	In-house
	SASS-001 (S-600918 + Concomitant drug X)	P2X3 receptor inhibitor (oral) + Mechanism of Concomitant drug	Sleep Apnea with a Central Component	Phase II	S-600918: In-house	Shionogi-Apnimed Sleep Science, LLC (USA)
	S-606001	Glycogen synthase 1 (GYS1) inhibitor (oral)	Pompe disease	Phase II	Maze (USA)	In-house
	SDS-881	AI Programmed Medical Device for Conversational Cognitive Function Testing	Cognitive impairment in dementia	Phase III	FRONTEO (Japan)	In-house
	S-898270	Phosphodiesterase 4D (PDE4D) Inhibitors	Alzheimer's Disease	Phase I	In-house	In-house
	SASS-002 (Sulthiame)	Carbonic anhydrase inhibitor	Obstructive Sleep Apnea	Phase II	Desitin	Shionogi-Apnimed Sleep Science, LLC (USA)
	Tapinarof	Aryl hydrocarbon receptor (AhR) modulating agent (Topical)	Atopic dermatitis in Pediatric Patients	NDA submission: Japan (Oct. 2025)	Dermavant (Switzerland)	In-house
			Atopic dermatitis in infant Patients	Phase III	Dermavant (Switzerland)	In-house
	Cantharidin [YCANTH®topical solution0.71%]	Treatment for viral warts (Topical)	Molluscum Contagiosum	Approval: Japan (Sep. 2025)	Verrica (USA)	In-house
	Cantharidin		Common Warts	Phase Ⅲ	Verrica (USA)	In-house (Japan) /Verrica (USA)
	TO-210	Peroxisome proliferator-activated receptor γ (PPARγ) modulating agent (Topical)	Acne vulgaris	Phase III	Nogra (Ireland)	In-house
	TO-203 [MITICURE®House Dust Mite Sublingual Tablets]	Allergen Immunotherapy (Sublingual tablet)	House dust mite inducedallergic asthma	Phase II/III	ALK (Denmark)	In-house
	TO-209	Allergen Immunotherapy (Sublingual tablet)	Grass pollen-induced allergic rhinitis	Phase III	ALK (Denmark)	In-house
	S-051051 (JTE-051)	Tropomyosin Receptor Kinase A (TrkA) /Interleukin-2 inducible T-cell kinase (ITK) inhibitor (oral)	Interstitial cystitis/Bladder pain syndrome, Autoinflammatory/Autoimmune diseases	Phase II	In-house	In-house
	S-662662 (JTT-662)	Sodium-Glucose Co-transporter1 (SGLT1) inhibitor (oral)	Hypertrophic cardiomyopathy	Phase I	In-house	In-house
	S-861861 (JTT-861)	Pyruvate dehydrogenase kinase (PDHK) inhibitor (oral)	Chronic heart failure	Phase II	In-house	In-house
	S-064064 (JTC-064)	PDHK inhibitor (oral)	Neurodegenerative disease	Phase I	In-house	In-house
	S-161161 (JTV-161)	Proto-oncogene serine/ threonine-protein kinase1 (Pim-1) inhibitor (oral)	Pulmonary arterial hypertension	Phase I	In-house	In-house
	S-162162 (JTE-162)	NLR family pyrin domain containing 3 (NLRP3) inhibitor (oral)	Autoinflammatory/ Autoimmune diseases	Phase I	In-house	In-house
	S-261261 (JTV-261)	Phospholipase D1/2 (PLD1/2) inhibitor (oral)	Thrombosis	Phase I	In-house	In-house
	S-262262 (JTC-262)	NLRP3 inhibitor (oral)	Neurodegenerative disease	Phase I	In-house	In-house
	S-263263 (JTV-263)	Hematopoietic Prostaglandin D Synthase (H-PGDS) inhibitor (oral)	Peripheral artery disease	Phase I	In-house	In-house
	S-461461 (JTE-461)	Mas-related G protein-coupled receptor X2 (MRGPRX2) antagonist (oral)	Chronic spontaneous urticaria	Phase I	In-house	In-house

<Out-Licensing Activity>

Generic name/Code No. [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Baloxavir marboxil [USA:Xofluza™] [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection (pediatric, < 1 year old)	Approval: EU (May.2025)	In-house	In-house/ Roche (Switzerland)
		Influenza virus infection (transmission)	NDA submission: USA (Nov. 2024)	In-house	In-house/ Roche (Switzerland)
S-723595 (TLC-3595)	Acetyl-CoA carboxylase 2 inhibitor (oral)	Type 2 diabetes	Phase IIa	In-house	OrsoBio, Inc. (USA)
S-365598	Integrase inhibitor (ultra long-acting injection)	HIV infection	Phase IIa	In-house	SHIONOGI-ViiV Healthcare LLC
Delgocitinib	Janus kinase (JAK) inhibitor (Topical)	Chronic hand eczema	Approval: EU (Sep. 2024), USA (Jul. 2025) NDA submission: Mainland China (Sep. 2025)	In-house	LEO Pharma (Denmark)
		Chronic hand eczema in adolescents	MAV submission: EU (Nov. 2025)	In-house	LEO Pharma (Denmark)
		Palmoplantar pustulosis	Phase IIa	In-house	LEO Pharma (Denmark)
		Lichen sclerosus	Phase Ⅲ	In-house	LEO Pharma (Denmark)
	JAK inhibitor (eye drop)	Ophthalmology disease	Phase II	In-house	ROHTO (Japan)
Enarodustat	Hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor (oral)	Anemia associated with chronic kidney disease in hemodialysis patients	Approval: Korea (Nov. 2022) , Mainland China (Sep. 2025)	In-house	JW Pharmaceutical (Korea)/ Salubris (Mainland China)
		Anemia associated with chronic kidney disease in peritoneal dialysis patients	Approval: Mainland China (Sep. 2025)	In-house	Salubris (Mainland China)
		Anemia associated with chronic kidney disease in non-dialysis patients	Approval: Mainland China (Jun. 2023)	In-house	Salubris (Mainland China)

Since October 27, 2025

Change	Cefiderocol (Tosilate Sulfate Hydrate): NDA submission: China→ Approval
	S-268024: Phase III→ NDA submission
	S-268023: Phase III→ Deleted
	Ensitrelvir (Treatment of COVID-19 12 years old and older): NDA submission: Taiwan→ deleted
	Zuranolone: NDA submission→ Approval
	Cantharidin (Common Warts): Phase II→Phase III
Add	S-567123 (Prevention of COVID-19): Phase I
	Ensitrelvir (Post exposure prophylaxis of COVID-19): NDA submission: Taiwan (Oct. 2025)
	Ensitrelvir (Treatment of COVID-19 Pediatric, 0 to 5 years): Phase III
	S-051051 (JTE-051): Phase II
	S-662662 (JTT-662): Phase I
	S-861861 (JTT-861): Phase II
	S-064064 (JTC-064): Phase I
	S-161161 (JTV-161): Phase I
	S-162162 (JTE-162): Phase I
	S-261261 (JTV-261): Phase I
	S-262262 (JTC-262): Phase I
	S-263263 (JTV-263): Phase I
	S-461461 (JTE-461): Phase I
	Delgocitinib (Chronic hand eczema): Approval: EU (Sep. 2024), USA (Jul. 2025), NDA submission: Mainland China (Sep. 2025)
	Delgocitinib (Chronic hand eczema in adolescents): MAV submission: EU (Nov. 2025)
	Delgocitinib (Palmoplantar pustulosis): Phase IIa
	Delgocitinib (Lichen sclerosus): Phase III
	Delgocitinib (Ophthalmology disease): Phase II
	Enarodustat (Anemia associated with chronic kidney disease in hemodialysis patients): Approval: Korea (Nov. 2022), Mainland China (Sep. 2025)
	Enarodustat (Anemia associated with chronic kidney disease in peritoneal dialysis patients): Approval: Mainland China (Sep. 2025)
	Enarodustat (Anemia associated with chronic kidney disease in non-dialysis patients): Approval: Mainland China (Jun. 2023)