

## 10. Pipeline (as of May 12, 2025)

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:Fetroja®]	Cell-wall synthesis inhibition (injection)	Gram-negative infection(pediatric)	Phase III	In-house	In-house
			Gram-negative infection	Phase III NDA submission: China (Aug. 2024) 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)	NDA submission: Japan (Aug. 2018)	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-268023	Vaccine (muscular injection)	Prevention of COVID-19	Phase III	In-house	In-house
	S-268024	Vaccine (muscular injection)	Prevention of COVID-19	Phase III	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: Taiwan (Jan. 2025) NDA withdrawal: Singapore	In-house	Japan, global, Taiwan: In-house South Korea: In-house/Ildong Singapore: In-house/Juniper
			Treatment of COVID-19 (Children, 5 to 11 years)	Phase III	In-house	In-house
			Post exposure prophylaxis of COVID-19	NDA submission: Japan (Mar. 2025)	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	In-house	In-house
	Zuranolone	GABA <sub>A</sub> receptor positive allosteric modulator (oral)	Depression	NDA submission: Japan (Sep. 2024)	Sage (USA)	In-house/ Sage
	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
		Cancer peptide vaccine (injection)	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
	S-588210	Cancer peptide vaccine (injection)	Solid tumor	Phase I	OncoTherapy Science, Inc. (Japan)	In-house

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QOL Diseases	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
	Redasentide Trifluoroacetate	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Phase IIb	StemRIM (Japan)	In-house
		Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	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-Apimed Sleep Science, LLC (USA)
	S-606001	Glycogen synthase 1 (GYS1) inhibitor (oral)	Pompe disease	Phase I	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

<Out-Licensing Activity>

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Baloxavir marboxil [USA:Xofluza <sup>TM</sup> ] [Japan:Xofluza <sup>TM</sup> ]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection (pediatric, < 1 year old)	NDA Submission: EU (Jun. 2024)	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

Since January 31, 2025

Change	Ensitrelvir Fumaric Acid(Prevention): Phase III→Japan: NDA submission
	S-892216(oral): Phase I→ Phase II
	SDT-001: Japan: NDA submission→ Approval
Add	S-268024: Phase III
	S-892216(long-acting injection): Phase I
	SDS-881 : Phase III