

## 10. Pipeline (as of January 31, 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	Global: Phase III (pediatric)	In-house	In-house
	Cefiderocol Tosilate Sulfate Hydrate [US, Japan: Fetroja®] [EU:Fetroja®]	Cell-wall synthesis inhibition (injection)	Gram-negative infection	China: NDA submission (Aug. 2024) China: Phase III	In-house	Ping An-Shionogi (China)
	Cefiderocol Tosilate Sulfate Hydrate [US, Japan: Fetroja®] [EU:Fetroja®]	Cell-wall synthesis inhibition (injection)	Gram-negative infection	Australia: MAA submission (Dec. 2024)	In-house	In-house
	Baloxavir marboxil [USA:Xofluza™] [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan: NDA submission (body weight <20kg) (Aug. 2018)	In-house	In-house/ Roche (Switzerland)
	S-268019 [Japan:Covgoze®]	Vaccine (muscular injection)	Prevention of COVID-19	Japan: Approval (Jun. 2024) Japan: Phase III	In-house	In-house
	S-268019 [Japan:Covgoze®]	Vaccine (muscular injection)	Prevention of COVID-19 (Adolescent)	Japan: Phase II/III	In-house	In-house
	S-268019 [Japan:Covgoze®]	Vaccine (muscular injection)	Prevention of COVID-19 (Children, 5 to 11 years)	Japan: Phase I/II/III	In-house	In-house
	S-268023	Vaccine (muscular injection)	Prevention of COVID-19	Japan: Phase III	In-house	In-house
	Ensitrelvir Fumaric Acid [Japan:Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19 (12 years old and older)	Japan: Phase III Global: Phase III South Korea: NDA withdrawal Taiwan: NDA submission (Jan. 2025) Singapore: NDA submission (Dec. 2023)	In-house	Japan, global, Taiwan In-house South Korea: In-house/Ildong Singapore: In-house/Juniper
	Ensitrelvir Fumaric Acid [Japan:Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19 (Children, 5 to 11 years)	Japan: Phase III	In-house	In-house
	Ensitrelvir Fumaric Acid [Japan:Xocova®]	3CL protease inhibitor (oral)	Prevention of COVID-19	Global: Phase III	In-house	In-house
	Olorofim	Dihydroorotate dehydrogenase (DHODH) inhibition (oral)	Invasive aspergillosis	Global: Phase III	F2G(UK)	In-house/ F2G
	S-892216	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: Phase I	In-house	In-house
	S-337395	RNA dependent RNA polymerase inhibitor (oral)	Treatment of RSV infection	Japan: Phase I Europe: Phase II	In-house/ UBE	In-house/ UBE
	S-743229	Cell-wall synthesis inhibition (oral)	Complicated urinary tract infections, including pyelonephritis	USA: Phase I Australia: Phase I	In-house/ Qpex	In-house/ Qpex
	S-649228	Cell-wall synthesis inhibition (injection)	Gram-negative infection	USA: Phase I	In-house/ Qpex	In-house/ Qpex
QOL Diseases	Naldemedine tosilate [Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, powder)	Opioid-induced constipation (pediatric)	Europe: Phase I/II	In-house	In-house
	Naldemedine tosilate [Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral)	Opioid-induced constipation	China: Phase III	In-house	Ping An-Shionogi (China)
	Zuranolone	GABA <sub>A</sub> receptor positive allosteric modulator (oral)	Depression	Japan: NDA submission (Sep. 2024)	Sage (USA)	In-house/ Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Treatment of ADHD (pediatric)	Japan: NDA submission (Feb. 2024)	Akili (USA)	In-house/ Akili
	Zatolmilast	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	USA: Phase II/III	Tetra (USA)	In-house/ Tetra
	Zatolmilast	PDE4D negative allosteric modulator (oral)	Jordan syndrome	USA: Phase II	Tetra (USA)	In-house/ Tetra
	Zatolmilast	PDE4D negative allosteric modulator (oral)	Alzheimer's disease	USA: Phase II Japan: Phase II	Tetra (USA)	In-house/ Tetra
	Resiniferatoxin	TRPV1 agonist (Intra-articular injection)	Pain associated with osteoarthritis of knee	Global: Phase III	Grünenthal (Germany)	Grünenthal
	S-151128	Nav1.7 inhibitor (injection)	Chronic pain	Japan: Phase I	In-house	In-house
	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto (Japan)	In-house/ Rohto
	S-309309	Monoacylglycerol acyltransferase 2 inhibitor (oral)	Obesity	USA: Phase II	In-house	In-house
	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan: Phase III	OncoTherapy Science, Inc. (Japan)	In-house

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QOL Diseases	S-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan,Europe: Phase II	OncoTherapy Science, Inc. (Japan)	In-house
	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-588210	Cancer peptide vaccine (injection)	Solid tumor	UK: Phase I	OncoTherapy Science, Inc. (Japan)	In-house
	S-222611 (Epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe: Phase I/II	In-house	In-house
	SR-0379	Promote granulation formation (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan: Phase III	FunPep (Japan)	In-house/ FunPep
	Redasentide Trifluoroacetate	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Global: Phase IIb	StemRIM (Japan)	In-house
	Redasentide Trifluoroacetate	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Epidermolysis bullosa	Japan: Phase II	StemRIM (Japan)	In-house
	S-531011	anti-CCR8 antibody (injection)	Solid tumor	Japan,USA: Phase Ib/II	In-house	In-house
	S-740792	New mechanism of action (oral)	Walking impairment associated with multiple sclerosis	USA: Phase I	In-house	In-house
	SASS-001 (S-600918+Concomitant drug X)	P2X3 receptor inhibitor (oral) + Mechanism of Concomitant drug	Sleep Apnea Syndrome	USA: Phase II	S-600918: In-house	Shionogi-Apnimed Sleep Science, LLC (USA)
	S-606001	Glycogen synthase 1 (GYS1) inhibitor	Pompe disease	Japan: Phase I	Maze (USA)	In-house

<Out-Licensing Activity>

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Baloxavir marboxil [USA:Xofluza™] [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	EU: NDA Submission (pediatric, < 1 year old) (Jun. 2024) USA: NDA submission (Nov.2024) (transmission)	In-house	In-house/ Roche (Switzerland)
S-723595 (TLC-3595)	Acetyl-CoA carboxylase 2 inhibitor (oral)	Type 2 diabetes	New Zealand: Phase IIa	In-house	OrsoBio, Inc. (USA)
S-365598	Integrase inhibitor (ultra long-acting injection)	HIV infection	Global: Phase IIa	In-house	SHIONOGI-ViiV Healthcare LLC

Since October 28, 2024

Change	Baloxavir marboxil (transmission): Global Phase III→USA: NDA submission (Nov.2024)
	Ensitrelvir Fumaric Acid: South Korea: NDA submission→NDA withdrawal
Add	Cefiderocol Tosilate Sulfate Hydrate: Australiz: MAA
	Ensitrelvir Fumaric Acid: Taiwan: NDA submissionm
	Zatolmilast(Jordan syndrome): USA: Phase II