

10. Pipeline (as of October 28, 2024)

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:Fetrocra [®]]	Cell-wall synthesis inhibition (injection)	Gram-negative infection	Global: Phase III (pediatric)	In-house	In-house
	Cefiderocol Tosilate Sulfate Hydrate [US, Japan: Fetroja [®]] [EU:Fetrocra [®]]	Cell-wall synthesis inhibition (injection)	Gram-negative infection	China: NDA submission (Aug.2024) China: Phase III	In-house	Ping An-Shionogi (China)
	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 submission Singapore: NDA submission (Dec. 2023)	In-house	In-house
	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 _A 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
	Zatoimilast	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	USA: Phase II/III	Tetra(USA)	In-house/ Tetra
	Zatoimilast	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
	S-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan,Europe: Phase II	OncoTherapy Science, Inc. (Japan)	In-house

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QOL Diseases	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
	S-600918 + Concomitant drug X	P2X3 receptor inhibitor (oral) + Mechanism of Concomitant drug X	Sleep Apnea Syndrome	USA: Phase II	S-600918: In-house	Shionogi- Aonimed 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	Global: Submitted in EU (pediatric, < 1 year old) (Jun. 2024) Global: Phase III (transmission)	In-house	In-house/ Roche (Switzerland)
S-723595 (TLC-3595)	Acetyl-CoA carboxylase 2 inhibitor (oral)	Type 2 diabetes	New Zealand: Phase II a	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 July 29, 2024

Change	Cefiderocol Tosilate Sulfate Hydrate: China: Phase III → NDA submission, Phase III
	Zuranolone: Japan: Phase III → NDA submission
Add	S-740792: USA: Phase I
	S-600918 + Concomitant drug X: USA: Phase II
	S-606001: Japan: Phase I