

### 3. Pipeline (as of January 31, 2024)

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate) [US:Fetroja®] [EU:Fetroja®]	Cell-wall synthesis inhibition (injection)	USA: Complicated urinary tract infections, including pyelonephritis and nosocomial pneumonia Europe: Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options Japan: Various infectious diseases caused by Gram-negative bacteria that are resistant to carbapenem antibiotics Taiwan: Infections due to aerobic Gram-negative bacteria in adult patients with limited treatment options	Global: Phase III (pediatric) Japan: Approval (Nov. 2023) Taiwan: NDA submission (Dec. 2022)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan: Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan: NDA submission (body weight <20kg) (Aug. 2018) Taiwan: sNDA submission (5 to 11 years old) (Jul. 2023)	In-house	SHIONOGI/ Roche (Switzerland)
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan: NDA submission (Nov. 2022) Japan: Phase III Global: Phase III	In-house	In-house
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19 (Adolescent)	Japan: Phase II/III	In-house	In-house
	S-268019	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
	S-217622 (Ensirelvir Fumaric Acid) [Japan: Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: Approval under the Emergency Regulatory Approval System (Nov. 2022) Normal NDA submission (June 2023) Japan: Phase II/III Global: Phase III South Korea: NDA submission Singapore: NDA submission (Dec. 2023)	In-house	In-house
	S-217622 (Ensirelvir Fumaric Acid) [Japan: Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19 (Children, 5 to 11 years)	Japan: Phase III	In-house	In-house
	S-217622 (Ensirelvir Fumaric Acid) [Japan: Xocova®]	3CL protease inhibitor (oral)	Prevention of COVID-19	Global: Phase III	In-house	In-house
	F901318 (Olorofim)	Dihydroorotate dehydrogenase (DHODH) inhibition (oral)	Invasive aspergillosis	Global: Phase III	F2G (UK)	SHIONOGI/ 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	SHIONOGI/ UBE
	S-743229	Cell-wall synthesis inhibition (oral)	Complicated urinary tract infections, including pyelonephritis	USA: Phase I Australia: Phase I	In-house/ Qpex	SHIONOGI/ Qpex

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Pain/CNS	S-297995 (naldemedine tosilate) [Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, powder)	Opioid-induced constipation (pediatric)	Europe: Phase I/II	In-house	In-house
	S-812217 (Zuranolone)	GABA <sub>A</sub> receptor positive allosteric modulator (oral)	Depression	Japan: Phase III	Sage (USA)	SHIONOGI/ Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Inattention symptom in ADHD patients (pediatric)	Japan: Phase III	Akili (USA)	SHIONOGI/ Akili
	BPN14770 (Zatolmilast)	PDE4D negative allosteric modulator(oral)	Fragile X syndrome	USA: Phase II/III	Tetra (USA)	SHIONOGI/ Tetra
	BPN14770 (zatolmilast)	PDE4D negative allosteric modulator(oral)	Alzheimer's disease	USA: Phase II Japan: Phase II	Tetra (USA)	SHIONOGI/ Tetra
	GRT7039 (Resiniferatoxin)	TRPV1 agonist (Intra-articular injection)	Pain associated with osteoarthritis of knee	Global: Phase III	Grünenthal (Germany)	Grünenthal
	S-151128	New mechanism of action	Chronic pain	Japan: Phase I	In-house	In-house
Frontier	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto(Japan)	SHIONOGI/ 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
	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)	SHIONOGI/ FunPep
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Global: Phase IIb	StemRIM (Japan)	In-house
	S-005151 (Redasemtide 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

<Out-Licensing Activity>

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S-033188 (Baloxavir marboxil) [USA:Xofluza™]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	USA: NDA submission (pediatric, >1 year old) (Mar. 2020) Global: Phase III (pediatric, < 1 year old) Global: Phase III (transmission)	In-house	SHIONOGL/Roche (Switzerland)
S-555739 (Asapirant)	Prostaglandin D2 DP1 receptor antagonist (oral)	Control of the aggravation of COVID-19	USA: Phase II	In-house	BioAge Labs, Inc. (USA)
S-723595 (TLC-3595)	Acetyl-CoA carboxylase 2 inhibitor (oral)	Type 2 diabetes	New Zealand: PhaseIIa	In-house	OrsoBio, Inc.(USA)
S-365598	Integrase inhibitor (ultra long-acting injection)	HIV infection	USA: Phase I	In-house	SHIONOGL-ViiV Healthcare LLC

Since Oct.31, 2023

Change	S-649266:Japan:NDA submission(Mar.2022)→ Approval (Nov.2023)(Change of phase)
	S-217622:Singapore: NDA submission (Dec. 2023)(Change of phase)
	S-337395:Europe: PhaseII(Change of phase)
	S-743229:Australia: Phase I(Change of phase)
	S-268023:Japan: Phase III(Compound added to the list)