3. Pipeline (as of February 1, 2021)

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：Fetcroja®]	Cell-wall synthesis inhibition (injection)	USA:Complicated urinary tract infections, including pyelonephritis and nosocomial pneumonia with no or limited treatment options Europe:Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options	Global:PhaseIII (pediatric) USA:Approval (cUTI) (Nov.2019) Approval (Nosocomial pneumonia) (Sep.2020) Europe: Approval (Apr.2020)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan:Approval (body weight ≧20kg) (Sep.2018) Japan:NDA submission (body weight <20kg) (Aug.2018) Japan:PhaseIII completion (high dosage for children)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection (prophylaxis)	Japan:Approval (body weight≧20kg) (Nov.2020)	In-house	Shionogi/Roche (Switzerland)
	S-648414	Not disclosed (oral)	HIV infection	USA,Japan:PhaseI	In-house	In-house
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan:PhaseI/II	In-house	In-house
Pain/CNS	S-297995 (naldemedine tosilate) [US/Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, powder)	Opioid-induced constipation(pediatric)	Europe:PhaseI/II	In-house	In-house
	S-297995 (naldemedine tosilate)	Peripheral opioid receptor antagonist (oral)	Postoperative ileus	USA:PhaseII	In-house	In-house
	S-120083	Not disclosed (oral)	Inflammatory pain	Japan:PhaseI USA:PhaseII	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Not disclosed (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	S-117957	Not disclosed (oral)	Insomnia	USA:PhaseI	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-600918	$P2X_3$ receptor antagonist (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	S-600918	$P2X_3$ receptor antagonist (oral)	Refractory/unexplained chronic cough	Global:PhaseII	In-house	In-house
	S-600918	$P2X_3$ receptor antagonist (oral)	Sleep Apnea Syndrome	Japan:PhaseII	In-house	In-house
	S-637880	Not disclosed (oral)	Neuropathic Low Back pain	Japan:PhaseII	In-house	In-house
	LY248686 (duloxetine hydrochloride) [Cymbalta®]	SNRI (Serotonin–norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan:PhaseIII	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-812217 (Zuranolone)	GABAA receptor positive allosteric modulator (oral)	Depression	Japan:PhaseII	Sage (USA)	Shionogi/Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Inattention symptom in ADHD patients (pediatric)	Japan:PhaseII	Akili (USA)	Shionogi/Akili
	BPN14770	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	USA:PhaseII	Tetra (USA)	Shionogi/Tetra
	BPN14770	PDE4D negative allosteric modulator (oral)	Alzheimer's disease	USA:PhaseII Japan:PhaseI	Tetra (USA)	Shionogi/Tetra

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan:PhaseII USA:PhaseI	In-house	In-house
	S-707106	Insulin sensitizer (oral)	Type 2 diabetes	USA:PhaseIIa	In-house	In-house
	ADR-001	Human mesenchymal stem cells（injection）	Decompensated liver cirrhosis	Japan:PhaseI/II	Rohto	Shionogi/Rohto
	S-723595	Acetyl-CoA carboxylase 2 inhibitor (oral)	NASH	Japan:PhaseI	In-house	In-house
Frontier	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan:PhaseIII	OncoTherapy Science, Inc. (Japan)	In-house
	S-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan,Europe:PhaseII	OncoTherapy Science, Inc. (Japan)	In-house
	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe:PhaseI/II	OncoTherapy Science, Inc.(Japan)	In-house
	S-588210	Cancer peptide vaccine (injection)	Solid tumor	UK:PhaseI	OncoTherapy Science, Inc.(Japan)	In-house
	S-222611 (epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe:PhaseI/II	In-house	In-house
	S-770108	Antifibrotic (inhalation)	Idiopathic pulmonary fibrosis	Japan:PhaseI	In-house	In-house
	SR-0379	Promote granulation formation (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan:PhaseII	FunPep (Japan)	Shionogi/FunPep
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Japan:PhaseII	StemRIM (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Epidermolysis bullosa	Japan:PhaseII (preparing NDA submission)	StemRIM (Japan)	In-house

<Out-Licensing Activity>

Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
S/GSK1265744 LAP*1 (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	(CAB*2 LAP+RPV*3 LAP 2-drug regimen for treatment) Canada:Approval(Mar.2020) USA:Approval (Jan. 2021) Europe:Approval (Dec. 2020) (CAB LAP for prevention) Global:PhaseIII	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK) for treatment Collaboration among ViiV,HPTN,NIAID and Gilead Sciences, Inc.(USA)for prevention
S-0373	Non-peptide mimetic of TRH (oral)	Spinocerebellar ataxia	Japan:PhaseIII	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA:Xofluza™]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	USA:Approval(Oct.2018) USA:Approval(high risk patients) (Oct.2019) USA:NDA submission(pediatric,≧ 1 year old) (Mar.2020) USA:Approval(Granule≧12 years old) (Nov.2020) USA:Approval(Prophylaxis≧12 years old) (Nov.2020) Europe:Approval(Treatment≧12 years old) (Prophylaxis≧12 years old)(Jan.2021) Global:PhaseIII(severe influenza virus infection) Global:PhaseIII(pediatric, < 1 year old) Global:PhaseIII(transmission)	In-house	Shionogi/Roche (Switzerland)

*1 Long acting parenteral formulation, *2 Cabotegravir, *3 Rilpivirine

Since Oct 30, 2020

Change of phase	S-033188(prophylaxis):Japan:NDA submission (Oct.2019) →Japan:Approval (body weight≧20kg) (Nov.2020)
	S-637880(Neuropathic pain):Japan:PhaseI→(Neuropathic Low Back pain):Japan:PhaseII
	S-033188(Granule≧12 years old)(Prophylaxis≧12 years old):USA:NDA submission (Mar.2020)→Approval (Nov.2020)
	S-033188(Treatment≧12 years old) (Prophylaxis≧12 years old):Europe: MAA submission(Nov. 2019)→Approval(Jan. 2021)
	S/GSK1265744 LAP(HIV infection) (2-drug regimen for treatmen):USA: NDA re-submission (Jul. 2020)→Approval (Jan. 2021)
	S/GSK1265744 LAP(HIV infection) (2-drug regimen for treatmen):Europe: MAA submission (Jul. 2019)→Approval (Dec. 2020)
Compound added to the list	S-268019(Prevention of COVID-19):Japan:PhaseI/II
	S-723595(NASH):Japan:PhaseI
Compound erased from the list	S/GSK1349572(dolutegravir) (DTG/3TC 2-drug fixed dose combination tablet):Approval (Aug. 2020)
	Oxycodone hydrochloride hydrate[OxyContin®]:Approval(Oct.2020)