3. Pipeline (as of July 29, 2019)

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate)	Cephem antibiotic (injection)	USA: Complicated urinary tract infections, including pyelonephritis Europe: Multidrug-resistant gram-negative bacterial infections	Global: Phase III USA: NDA submission (Dec.2018) Europe: MAA submission (Mar.2019)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: Approval (Feb.2018) Taiwan: NDA submission (Jun.2018)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral, granule)	Influenza virus infection	Japan: Approval (body weight ≧20kg) (Sep.2018) Japan: NDA submission (body weight <20kg) (Aug.2018) Japan: Phase III (new dosage for children)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection (prophylaxis)	Japan: Phase III	In-house	Shionogi/Roche (Switzerland)
Pain/CNS	S-297995 (naldemedine tosilate) [US/Japan:Symproic®] [EU: Rizmoic®]	Peripheral opioid receptor antagonist (oral, granule)	Opioid-induced constipation(pediatric)	Japan: Phase I	In-house	In-house
	S-877503 (guanfacine hydrochloride) [Intuniv®]	Alpha-2A-adrenergic receptor agonist (oral)	ADHD (adult)	Japan:Approval (Jun.2019)	Shire (Ireland)	Shionogi/Shire
	S-120083	Analgesic agent for inflammatory pain (oral)	Inflammatory pain	Japan: Phase I USA: Phase II	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-117957	Agent for insomnia (oral)	Insomnia	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-600918	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-600918	Antitussive agent (oral)	Refractory/unexplained chronic cough	Japan: Phase II	In-house	In-house
	S-637880	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	LY248686 (duloxetine hydrochloride) [Cymbalta®]	SNRI (Serotonin–norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan: Phase III	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-812217	GABAA receptor positive allosteric modulator (oral)	Depression	Japan: Phase I	Sage (USA)	Shionogi/Sage
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan: Phase II USA: Phase I	In-house	In-house
	S-707106	Insulin sensitizer (oral)	Type 2 diabetes	USA: Phase IIa	In-house	In-house
	ADR-001	Human mesenchymal stem cells(injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto	Shionogi/Rohto
Frontier	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

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Frontier	S-525606	Sublingual tablet of Japanese cedar allergen extracts for immunotherapy (sublingual)	Allergic rhinitis caused by Japanese cedar allergen	Japan: Phase II	Stallergenes (France)	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
	S-770108	Anti-fibrosis (inhalation)	Idiopathic pulmonary fibrosis	Japan: Phase I	In-house	In-house
	SR-0379	Cutaneous ulcer (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan: Phase II	FunPep (Japan)	In-house
	S-005151	Stroke (injection)	Stroke	Japan: Phase Ⅱ	StemRIM (Japan)	In-house

<Out-Licensing Activity>

Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
S/GSK1349572 (dolutegravir)	Integrase inhibitor (oral)	For the treatment of HIV infection	(DTG*1/3TC*2 2-drug fixed dose combination tablet) USA: Approval (Apr.2019, naïve patients) Europe: Approval (Jul.2019, naïve and switch patients) Global: Phase III (switch patients)	Shionogi-ViiV Healthcare LLC	Viiv Healthcare Ltd. (UK)
S/GSK1265744 LAP*3 (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	(CAB*4 LAP+RPV*5 LAP 2-drug regimen for treatment) USA: NDA submission (Apr.2019) (CAB LAP for prevention) Global: Phase III	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: Phase III	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA: Xofluza™]	Anti-influenza virus infection (oral)	Influenza virus infection	USA: Approval (Oct.2018) USA: sNDA submission acceptance (high risk patients, Mar.2019) Global: Phase III (severe influenza virus infection) Global: Phase III (pediatric)	In-house	Shionogi/Roche (Switzerland)

*1: Dolutegravir, *2: Lamivudine, *3: Long acting parenteral formulation, *4: Cabotegravir, *5: Rilpivirine

<Drugs to acquire new indication requested by the Ministry of Health, Labour and Welfare>

Generic name [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Oxycodone hydrochloride hydrate [OxyContin®]	Natural opium alkaloids (oral)	For the treatment of moderate to severe chronic pain	Japan; NDA re-submission (May 2019)	Napp Pharmaceuticals Limited (UK)	In-house

Since May 9, 2019

Change of phase	S-877503 (adult) : Japan:NDA submission (Aug.2018) →Japan:Approval (Jun. 2019)
	ADR-001 : Added to the list
	S/GSK1349572(DTG/3TC 2-drug fixed dose combination tablet) : Europe:MAA submission (Sep.2018)→Europe:Approval (Jul.2019)
	Oxycodone hydrochloride hydrate : Japan:NDA submission (Nov.2016)→Japan:NDA re-submission (May 2019)
Compound erased from the list	S-297995 (adult) : USA, Japan: Approval (Mar.2017), Europe: Approval (Feb.2019)
	S-877489 : Japan: Approval (Mar.2019)
	S-888711 : Japan: Approval (Sep.2015), USA: Approval (Jul.2018), Europe: Approval (Feb.2019)