

Pipeline (as of Feb. 2018)

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate)	Cepem antibiotic (injection)	Multidrug-resistant Gram-negative bacterial infections	Global: Phase III USA: NDA submission (in preparation)	In-house	In-house
	S-033188 (baloxavir marboxil)	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: NDA submission (Oct.2017) USA: NDA submission (in preparation) Global: Phase III	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil)	Anti-influenza virus infection (oral)	Influenza virus infection (pediatric)	Japan: NDA submission (Oct.2017)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil)	Anti-influenza virus infection (oral, granule)	Influenza virus infection	Japan: Phase III	In-house	Shionogi/Roche (Switzerland)
Pain/CNS	S-297995 (naldemedine tosilate) [Symproic [®]]	Peripheral opioid receptor antagonist (oral)	Opioid-induced constipation	USA, Japan: Approval (Mar.2017) Europe:MAA submission(Mar.2017)	In-house	In-house
	S-877489 (lisdexamfetamine mesilate)	DA and NE reuptake inhibitor/releaser of DA, NE (oral)	ADHD (pediatric)	Japan: NDA submission (Apr.2017)	Shire (Ireland)	Shionogi/Shire
	S-877503 (guanfacine hydrochloride) [Intuniv [®]]	Alpha-2A-adrenergic receptor agonist (oral)	ADHD (adult)	Japan: Phase III	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
	LY248686 (duloxetine hydrochloride) [Cymbalta [®]]	SNRI (Serotonin-norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan: Phase III	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
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
Frontier	S-888711 (lusutrombopag) [Japan: Mulpleta [®]]	Thrombopoetin (TPO) receptor agonist (oral)	Thrombocytopenia associated with chronic liver disease	Japan: Approval (Sep.2015) USA: NDA submission (Dec.2017) Europe:MAA submission(Jan.2018)	In-house	In-house
	S-524101 [Actair [®]]	Sublingual tablet of house-dust mite allergen extracts for immunotherapy (sublingual)	Pediatric patients with perennial allergic rhinitis caused by HDM	Japan: NDA submission (Mar.2017)	Stallergenes (France)	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-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

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Frontier	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe: Phase I/II	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

<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	USA: Approved (Nov.2017) Europe:MAA submission (Jun.2017) (DTG/rilpivirine 2-drug fixed dose combination tablet) Global: Phase III (DTG/3TC)	Shionogi-ViiV Healthcare LLC	Viiv Healthcare Ltd. (UK)
S/GSK1265744 LAP* (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	Global: Phase III (treatment) Global: Phase III (prevention)	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)
Janssen/Shionogi BACE inhibitor	BACE inhibitor (oral)	Alzheimer's disease	Global: Phase II/III	In-house	Janssen Pharmaceuticals, Inc. (USA)
Ospemifene [USA: Osphe [®]]	Selective estrogen receptor modulator (oral)	Vaginal dryness associated with postmenopausal VVA	USA: Phase III	QuatRx (USA)	Duchesnay(Canada)

*: Long acting parenteral formulation

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

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Oxycodone hydrochloride hydrate [OxyContin [®]]	Natural opium alkaloids (oral)	For the treatment of moderate to severe chronic pain	Japan: NDA submission (Nov.2016)	Napp Pharmaceuticals Limited (UK)	In-house

Since October 2017

Change of phase	S-033188: Japan: NDA submission(Oct.2017), Global: Phase III →Japan: NDA submission(Oct.2017), USA: NDA submission(in preparation), Global: Phase III				
	S-888711: Japan: Approval(Sep.2015), Global: NDA/MAA submission (in preparation) →Japan: Approval(Sep.2015), USA: NDA submission(Dec.2017), Europe:MAA submission(Jan.2018)				
	S/GSK1349572 DTG/rilpivirine 2-drug fixed dose combination tablet: Global: NDA/MAA submission →USA: Approved(Nov.2017), Europe:MAA submission(Jun.2017)				
Compound added to the list	S-033188(granule): Japan: Phase III				
	S-770108: Japan: Phase I				