

Pipeline (as of January 2012)

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Metabolic Syndrome	S-474474 (Irbesartan/trichlormethiazide combination)	Angiotensin receptor blocker/diuretic combination (Oral)	Hypertension	Japan: Phase III	Irbesartan: Sanofi (France) Trichlormethiazide: Shionogi	In-house
	S-2367 (Velneperit)	Neuropeptide Y Y5 receptor antagonist (Oral)	Obesity	Japan: Phase II	In-house	In-house
	S-707106	Insulin sensitizer (Oral)	Type 2 Diabetes	USA: Phase IIa	In-house	In-house
	S-234462	Neuropeptide Y Y5 receptor antagonist (Oral)	Obesity	USA: Phase I	In-house	In-house
Infectious Diseases	S-4661 (Doripenem hydrate) 【Finibax®】	Carbapenem antibiotic (Injection)	Pediatric infection	Japan: NDA submission (August 2011)	In-house	In-house
	S-349572 (Dolutegravir)	Integrase inhibitor (Oral)	HIV infection	Global: Phase III	Shionogi-ViiV Healthcare LLC	Shionogi-ViiV Healthcare LLC
	S-265744 LAP	Integrase inhibitor (Injection; Long acting parenteral formulation)	HIV infection	USA: Phase I	Shionogi-ViiV Healthcare LLC	Shionogi-ViiV Healthcare LLC
Pain	LY248686 (Duloxetine hydrochloride) 【Cymbalta®】	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)	Diabetic peripheral neuropathic pain	Japan: NDA submission (September 2009)	Eli Lilly and Company (USA)	Shionogi/Eli Lilly Japan K.K.
	S-811717 (Oxycodone hydrochloride hydrate) 【OxiFast®】	Natural opium alkaloids (Injection)	For the treatment of moderate to severe pain in patients with cancer pain	Japan: Approved (January 2012)	Napp Pharmaceuticals Limited (UK)	In-house
	S-297995	Peripheral opioid receptor antagonist (Oral)	Alleviation of opioid-induced adverse effect	USA: Phase IIb Japan: Phase IIb	In-house	In-house
	S-117957	Analgesic agent for neuropathic pain (Oral)	Neuropathic pain	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
Women's Health	PSD502 (Lidocaine/prilocaine)	Eutectic mixture of anesthetics (Metered-dose topical aerosol spray)	Premature ejaculation	USA, Europe: Phase III	Plethora Solutions Holdings PLC (UK)	Shionogi/Plethora Solutions Holdings PLC
	Ospemifene	Selective estrogen receptor modulator (Oral)	Post-menopausal vaginal atrophy	USA: NDA submission (in preparation)	QuatRx Pharmaceuticals Company (USA)	Shionogi/QuatRx Pharmaceuticals Company
Other	S-555739	Prostaglandin D2 receptor antagonist (Oral)	Allergic disease	Japan: Phase IIb USA: Phase I Europe: POM (Proof of Mechanism)	In-house	In-house
	S-524101	Sublingual tablet of house-dust mite allergen extracts for immunotherapy	Allergic rhinitis caused by house-dust mite allergen	Japan: Phase II (in preparation)	Stallergenes SA (France)	In-house
	S-888711	Small molecule TPO mimetic (Oral)	Thrombocytopenia	USA, Europe: Phase II Japan: Phase IIa	In-house	In-house
	S-288310	Cancer peptide vaccine (Injection)	Bladder cancer	Asia: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-488410	Cancer peptide vaccine (Injection)	Esophageal cancer	Japan: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-222611	HER2/EGFR dual inhibitor (Oral)	Malignant tumor	Europe: Phase Ib	In-house	In-house
	S-488210	Cancer peptide vaccine (Injection)	Head and neck squamous cell carcinoma	Europe: Phase I/II (in preparation)	OncoTherapy Science, Inc. (Japan)	In-house

<Out-Licensing Activity>

Code No. (Generic name)	Category (Administration)	Indication	Stage	Origin	Development
S-4661 (Doripenem hydrate)	Carbapenem antibiotic (Injection)	Bacterial infection	USA: Approval (October 2007) Complicated intra-abdominal infections, Complicated urinary tract infections including pyelonephritis NDA submission (June 2007) Hospital-acquired (nosocomial) pneumonia including ventilator-associated pneumonia Europe: Approval (July 2008)	In-house	Johnson & Johnson (USA)
S-3013 (Varespladib methyl)	Secretory PLA2(sPLA2) inhibitor (Oral)	Acute coronary syndromes	USA, Europe: Phase III	Shionogi/Eli Lilly and Company (USA)	Anthera Pharmaceuticals, Inc. (USA)
S-0373	Non-peptide mimetic of TRH (Oral)	Spinocerebellar ataxia	Japan: Phase II	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)

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

Generic name 【Product name】	Category (Administration)	Indication	Stage	Origin	Development
Metronidazole 【Flagyl [®] 】	Antibacterial and antiprotozoal agent (Oral)	Infections caused by anaerobic bacteria, Amebiasis, Giardiasis	NDA submission (in preparation)	Sanofi (France)	In-house
Metronidazole 【Flagyl [®] 】	Antibacterial and antiprotozoal agent (Oral or Intravaginal)	Bacterial vaginosis	NDA submission (in preparation)	Sanofi (France)	In-house
Lisinopril hydrate 【Longes [®] 】	ACE inhibitor (Oral)	Childhood hypertension	NDA submission (in preparation)	Merck & Co., Inc. (USA)/ AstraZeneca (UK)	Shionogi/ AstraZeneca
Ifosfamide 【Ifomide】	Antineoplastic agent (Injection)	Malignant lymphoma	NDA submission	Baxter (USA)	In-house
Sulfamethoxazole/trimethoprim combination 【Baktar [®] 】	Synthetic folate-antagonist/ anti-infectives combination (Oral)	Prophylaxis and treatment of <i>Pneumocystis carinii</i>	NDA submission (in preparation)	GSK (UK)/Shionogi	In-house
Oxycodone hydrochloride hydrate 【OxyContin [®] , OxiNorm [®] 】	Natural opium alkaloids (Oral)	For the treatment of moderate to severe chronic pain	Clinical trial (in preparation)	Napp Pharmaceuticals Limited (UK)	In-house
Duloxetine hydrochloride 【Cymbalta [®] 】	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)	Fibromyalgia	Phase III	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
Vancomycin hydrochloride 【Vancomycin】	Glycopeptide antibiotic (Drip infusion)	<Spectrum> Methicillin-resistant coagulase-negative staphylococcus, Penicillin-resistant enterococcus <Indication> Gram-positive bacteria-associated bloodstream infection (including intravascular catheter-related infection), Febrile neutropenia, Alternative agent in penicillin-allergic adults and children	To be determined	Eli Lilly (USA)	In-house

Since October 2011

Change of phase	S-811717: Japan: NDA submission (August 2011) → Approved (January 2012)
	Metronidazole 【Flagyl [®] 】: NDA submission (in preparation) → NDA submission
	Ifosfamide 【Ifomide】: Malignant lymphoma in childhood → Malignant lymphoma, NDA submission (in preparation) → NDA submission
	Oxycodone hydrochloride hydrate 【OxyContin [®] , OxiNorm [®] 】: To be determined → Clinical trial (in preparation)
	Duloxetine hydrochloride 【Cymbalta [®] 】: Clinical trial (in preparation) → Phase III
Compound added to the list	S-117957: USA: Phase I
	S-488210: Europe: Phase I/II (in preparation)
Compound erased	Cyclophosphamide hydrate 【Endoxan [®] 】: Approval (September 2011)