

Pipeline (as of February, 2010)

<In Japan>

Code No. (Generic name)	Category (Administration)	Indication	Stage	Origin	Development
S-021812 (Peramivir)	Neuraminidase inhibitor (Injection)	Influenza infection	Launch (January 2010)	BioCryst Pharmaceuticals, Inc. (USA)	In-house
LY248686 (Duloxetine hydrochloride)	S N R I (serotonin & noradrenaline reuptake inhibitor) (Oral)	Depression	Approval (January 2010)	Eli Lilly and Company (USA)	In-house
LY248686 (Duloxetine hydrochloride)	S N R I (serotonin & noradrenaline reuptake inhibitor) (Oral)	Diabetic peripheral neuropathic pain	NDA submission (September 2009)	Eli Lilly and Company (USA)	Co-development: Eli Lilly Japan K.K.
S-021812 (Peramivir)	Neuraminidase inhibitor (Injection)	Pediatric influenza infection	NDA submission (in preparation)	BioCryst Pharmaceuticals, Inc. (USA)	In-house
S-4661 (Doripenem hydrate)	Carbapenem antibiotic (Injection)	Pediatric infection	Phase III	In-house	In-house
S-4661 (Doripenem hydrate)	Carbapenem antibiotic (Injection)	Addition of new dosage regimen (1g t.i.d. for serious infection)	Phase III	In-house	In-house
S-811717 (Oxycodone hydrochloride)	Natural opium alkaloids (Injection)	For the treatment of moderate to severe pain in patients with cancer pain	Phase III	Napp Pharmaceutical Limited (UK)	In-house
S-013420 (Modithromycin)	Novel macrolide antibiotic (Oral)	Bacterial infection	Phase IIb	Enanta Pharmaceuticals, Inc. (USA)	In-house
NS75B (Cetrorelix pamoate)	Gonadotropin releasing hormone antagonist (Injection)	Benign prostatic hypertrophy	Phase IIb	Æterna Zentaris GmbH (Canada)	In-house
S-0139	Endothelin A receptor antagonist (Injection)	Cerebrovascular diseases	Phase IIa	In-house	In-house
S-555739	Prostaglandin D2 receptor antagonist (Oral)	Allergic disease	Phase IIa	In-house	In-house
S-2367 (Velneperit)	Neuropeptide Y Y5 receptor antagonist (Oral)	Obesity	Phase IIa	In-house	In-house
S-444823	Cannabinoid receptor agonist (Topical)	Atopic dermatitis	Phase IIa	In-house	In-house
S-288310	Peptide cancer vaccine (injection)	Bladder cancer	Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
S-888711	Small molecule TPO mimetic (Oral)	Thrombocytopenia	Phase I	In-house	In-house
S-297995	Peripheral opioid receptor antagonist (Oral)	Alleviation of opioid- induced adverse effect	Phase I	In-house	In-house

<Outside Japan>

Code No.	Category (Administration)	Indication	Stage	Origin	Development
S-2367 (Velneperit)	Neuropeptide Y Y5 receptor antagonist (Oral)	Obesity	USA: Phase IIb	In-house	In-house
S-349572/S-265744/S-247303	Integrase inhibitor (Oral)	HIV infection	USA, Europe: Phase IIb (the most advanced phase)	Shionogi & GlaxoSmithKline	Shionogi-GlaxoSmithKline Pharmaceuticals LLC (USA)
S-888711	Small molecule TPO mimetic (Oral)	Thrombocytopenia	USA: Phase II	In-house	In-house
S-555739	Prostaglandin D2 receptor antagonist (Oral)	Allergic disease	Europe: POM	In-house	In-house
S-0139	Endothelin A receptor antagonist (Injection)	Cerebrovascular diseases	Europe: Phase I	In-house	In-house
S-234462	Neuropeptide Y Y5 receptor antagonist (Oral)	Obesity	USA: Phase I	In-house	In-house
S-222611	Her2/EGFR dual inhibitor (Oral)	Malignant tumor	Europe: Phase Ib (in preparation)	In-house	In-house
S-707106	Insulin sensitizer (Oral)	Type 2 Diabetes	USA: Phase I (in preparation)	In-house	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 EU: Approval	In-house	Peninsula (USA) ↓ Johnson & Johnson (USA)
S-0373	Non-peptide mimetic of TRH (Oral)	Spinocerebellar ataxia	Japan : Phase II	In-house	Kissei Pharmaceutical Co., Ltd.
S-3013 (Varespladib methyl)	Secretory PLA2(sPLA2) inhibitor (Oral)	Acute coronary syndromes Mixed dyslipidemia	USA, EU: Phase IIb	Shionogi & Eli Lilly and Company (USA)	Anthera (USA)

Since November, 2009

Change of phase	S-021812<In Japan> : NDA submission → Launch
	LY248686<In Japan> (Depression) : NDA submission → Approval
	S-021812<In Japan> : Phase III (pediatric) → NDA submission (in preparation)
	S-2367<In Japan> : Phase IIa (in preparation) → Phase IIa
	S-444823<In Japan> : Phase IIa (in preparation) → Phase IIa
	S-888711<Outside Japan> : Phase II (in preparation) → Phase II
	S-234462<Outside Japan> : Phase I (in preparation) → Phase I
Compound added to the list	S-707106<Outside Japan> : Phase I (in preparation)

<Shionogi Pharma, Inc.>

Product (Generic name)	Category (Administration)	Indication	Stage	Origin	Development
PrandiMet (Repaglinide and metformin HCl)	Fast-acting insulin secretagogue and metformin; antihyperglycemic insulin sensitizer (Oral)	Type 2 Diabetes	Launch January 2009	Novo Nordisk	Novo Nordisk
Ulesfia (Benzyl alcohol)	Topical benzyl alcohol pediculocide (Topical lotion)	Head lice	Launch July 2009	Summers Laboratories, Inc	Summers Laboratories, Inc
Prenate DHA (Vitamins, minerals, DHA and metafolin)	Vitamins, minerals, metafolin (active form of folate), omega-3 fatty acids (Oral)	Prenatal DHA vitamin	Launch April 2009 (NDA not required)	Shionogi Pharma, Inc.	Shionogi Pharma, Inc.
Adrenaclick (Epinephrine)	(Single-dose epinephrine auto-injector)	Anaphylaxis	Launch January 2010	Shionogi Pharma, Inc.	Shionogi Pharma, Inc.
Glycopyrrolate (Glycopyrrolate oral solution)	Anticholinergic (Oral)	Chronic moderate-to-severe drooling in pediatric patients	USA: NDA filed September 2009	Shionogi Pharma, Inc.	Shionogi Pharma, Inc.
Clonidine HCL (Clonidine hydrochloride)	Centrally acting alpha adrenergic agonist (Oral)	Attention Deficit Hyperactivity Disorder (ADHD)	USA: sNDA filed October 2009	Addrenex Pharmaceuticals, Inc.	Shionogi Pharma, Inc. and Addrenex Pharmaceuticals, Inc.
Pravastatin/Fenofibrate (Pravastatin/fenofibrate combination)	Statin-HMG-CoA reductase inhibitors, fenofibrate lipid regulating agent (Oral)	Lowering non-HDL cholesterol and triglycerides	USA: NDA filed November 2009	Galephar, PR Inc / SMB Laboratories	Shionogi Pharma, Inc. and SMB Laboratories
Prenate Elite (Vitamin, minerals and metafolin)	Vitamins, minerals, metafolin (active form of folate) (Oral)	Prenatal Vitamin	USA: NDA not required	Shionogi Pharma, Inc.	Shionogi Pharma, Inc.
Jenloga XR (Clonidine hydrochloride)	Centrally acting alpha adrenergic agonist (Oral)	Hypertension	USA: Phase III trial completed	Addrenex Pharmaceuticals, Inc	Shionogi Pharma, Inc. and Addrenex Pharmaceuticals, Inc.
PSD502 (Lidocaine/prilocaine)	Eutectic mixture of anesthetics (Metered-dose topical aerosol spray)	Premature Ejaculation (PE)	Europe: Phase III trial completed; USA: Second and final Phase III trial completed	Plethora Solutions Holdings PLC	Shionogi Pharma, Inc. and Plethora Solutions Holdings PLC
ADX415	2 alpha specific adrenergic agonist (Oral)	Hypertension	USA: Phase II trial (in preparation)	Addrenex Pharmaceuticals, Inc.	Shionogi Pharma, Inc.

Since November, 2009

Change of phases	Adrenaclick (Epinephrine): Phase III trial → Launch
	Pravastatin/Fenofibrate (Pravastatin/fenofibrate combination): Phase III safety and efficacy study completed → NDA filed
	ADX415: Phase II → Phase II trial (in preparation)