

State of New Product Development (as of January 29, 2009)

1. Pipeline in Japan

(1) New Molecular Entities

Development code (Generic name)	Category (Indications)	Stage	Origin	Remarks
TA-8317 / ACREF (Fentanyl citrate)	Narcotic analgesic (Breakthrough cancer pain: oral transmucosal)	NDA filed (Aug. 2008)	US:Cephalon	
MCC-847 (Masilukast)	Leukotriene D4 antagonist (Asthma) (Allergic rhinitis)	Phase 3 Phase 2	UK: AstraZeneca	
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	Phase 3	US:Vertex	
APTA-2217 (Roflumilast)	PDE4 inhibitor (Asthma) (COPD)	Phase 2/3 Phase 2/3	Switzerland: Nycomed	Co-development -Nycomed, Switzerland
CNT0148 (Golimumab)	Anti-TNF α monoclonal antibody (Rheumatoid arthritis)	Phase 2/3	US:Centocor	Co-development -Janssen Pharma
FTY720 (Fingolimod hydrochloride)	Sphingosine-1-phosphate receptor modulator (Multiple Sclerosis)	Phase 2	In-house	Co-development -Novartis Pharma -Mitsui Sugar
MP-513	DPP4 Inhibitor (Type 2 Diabetes mellitus)	Phase 2	In-house	
MP-214 (Cariprazine)	D3/D2 antagonist (Schizophrenia)	Phase 2	Hungary: Gedeon- Richter	
MP-435	C5a antagonist (Rheumatoid arthritis)	Phase 1	In-house	
TA-6666	DPP4 inhibitor (Type 2 Diabetes mellitus)	Phase 1	In-house	
TA-7284	SGLT2 inhibitor (Diabetes mellitus)	Phase 1	In-house	

(2) Additional Indications

Development code (Generic name)	Category (Indications)	Stage	Origin	Remarks
Venoglobulin-IH (Polyethylene glycol treated human normal immunoglobulin)	Human immunoglobulin G (IgG2 deficiency)	sNDA filed (Dec. 1997)	In-house	
	(Polymyositis, Dermatomyositis*)	sNDA filed (May 2003)		
	(Hypo and gammagloblinemia: additional dose)	sNDA filed (Mar. 2008)		
	(Systemic Sclerosis)	Phase 3		
	(Myasthenia Gravis)	Phase 3		
Remicade (Infliximab(recombinant))	Anti-TNF α monoclonal antibody (Rheumatoid arthritis: dose escalation)	sNDA filed (Sep. 2007)	US:Centocor	
	(Psoriasis)	sNDA filed (Feb. 2008)		
	(Ankylosing spondylitis*)	sNDA filed (Sep. 2008)		
	(Ulcerative colitis)	Phase 3		
	(Crohn's disease: dose escalation)	Phase 3		
Valixa (Valganciclovir)	Antiviral (Post- transplantation cytomegalovirus infection)	sNDA filed (Jun. 2008)	Switzerland: Roche	
Ceredist (Taltirelin hydrate)	Spinocerebellar degeneration remedy (Orally disintegrating tablet: additional formulation)	sNDA filed (Jul. 2008)	In-house	
Modiodal (Modafinil)	Psychoneurotic agent (Obstructive sleep apnea)	Phase 3	US: Cephalon	Co-development -Alfresa Pharma
Anplag (Sarpogrelate hydrochloride)	5HT ₂ antagonist (Prevention of recurrence of cerebral infarction)	Phase 3	In-house	
Radicut (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	Phase 3	In-house	
Maintate (Bisoprolol)	Selective β ₁ antagonist (Chronic heart failure)	Phase 3	Germany: Merck KGaA	
Pazucross (Pazufloxacin mesilate)	Injectable quinolone synthetic antibacterial agent (Severe or intractable case: additional dose) (Sepsis, Pneumococcus)	Phase 3	Japan: Toyama Chemical	Co-development -Toyama Chemical
Cholebine (Colestimide(JAN))	New mode of action for diabetes treatment (Type 2 Diabetes mellitus)	Phase 2	In-house	
	Non-absorbed phosphate binder (Hyperphosphatemia)	Phase 1		

*: Orphan drug designated

2. Pipeline Overseas

(1) New Molecular Entities

Development code (Generic name)	Category (Indications)	Region	Stage	Origin	Region
MCI-196 (Colestilan(INN))	Non-absorbed phosphate binder (Hyperphosphatemia)	US, EU	Phase 3	In-house	
MP-146	Uremic toxin adsorbent (Chronic kidney disease)	US, EU	Phase 3	Japan:Kureha	
TA-6666	DPP4 inhibitor (Type 2 Diabetes mellitus)	US	Phase 2	In-house	
TA-5538	NK-1 receptor antagonist (Overactive bladder)	EU	Phase 2	In-house	
MCC-135 (Caldaret)	Intracellular Ca handling modulator (Myocardial infarction)	US, EU	Phase 2	In-house	
MCC-257	Neurotrophin enhancer (Diabetic neuropathy)	US	Phase 2	In-house	
MT-2832	Vitamin D analog (Secondary hyperparathyroidism)	Canada	Phase 2	Canada: Cytochroma	CTA018
TA-5493	p38 inhibitor (Rheumatoid arthritis, Psoriasis)	EU	Phase 1	In-house	
MCI-186 (Edaravone)	Free radical scavenger (Acute cerebral infarction)	EU	Phase 1	In-house	
MP-513	DPP4 inhibitor (Type 2 Diabetes mellitus)	US, EU	Phase 1	In-house	
GB-1057 (Human serum albumin [recombinant])	Recombinant human serum albumin (Stabilizing agent)	US	Phase 1	In-house	
TA-8995	CETP inhibitor (Dyslipidemia)	EU	Phase 1	In-house	
MP-124	PARP inhibitor (Acute Ischemic Stroke)	US	Phase 1	In-house	

(2) Additional Indications

Development code (Generic name)	Category (Indications)	Region	Stage	Origin	Remarks
MCI-9038 (Argatroban)	Thrombin inhibitor (Heparin-induced thrombocytopenia (HIT))	EU	Preparing for NDA	In-house	
	(HIT Patients undergoing percutaneous coronary intervention(PCI))	EU	Phase 3		

3. Licensing-out

Development code (Generic name)	Category (Indications)	Region	Stage	Licensee
FTY720 (Fingolimod hydrochloride)	Sphingosine 1-phosphate receptor agonist (Multiple sclerosis)	US, EU	Phase 3	Switzerland:Novartis Pharma
TA-1790 Avanafil	PDE5 inhibitor (Erectile dysfunction)	US	Phase 3	US:Vivus
		Korea	Phase 2	Korea:Choongwae Pharma
MKC-242	5-HT1A receptor agonist (Insomnia)	US	Phase 2	US:MediciNova
MCI-225	Norepinephrine reuptake inhibitor + 5-HT3 receptor antagonist (Diarrhea-predominant irritable bowel syndrome)	US	Phase 2	US:Dynogen Pharmaceuticals
MKC-733	5-HT3 receptor agonist (Constipation-predominant irritable bowel syndrome) (Gastroesophageal reflux disease at nighttime)	US	Phase 2	US:Dynogen Pharmaceuticals
		US	Phase 1	
TA-2005 Carmoterol	Long-acting β 2 agonist (Asthma, COPD)	EU	Phase 2	Italy:Chiesi Farmaceutici
T-0047 (Firatergrast)	Cell adhesion inhibitor [α 4 β 7/ α 4 β 1 inhibitor] (Multiple sclerosis)	EU	Phase 2	UK:GlaxoSmithKline
MKC-231	Neurogenesis enhancer (Depression/Anxiety)	US	Phase 2	US:BrainCells
TA-7284	SGLT2 inhibitor (Diabetes mellitus, Obesity)	EU, US	Phase 2	US: Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Y-39983	ROCK (rho-kinase) inhibitor (Glaucoma)	Japan	Phase 2	Japan: Senju Pharmaceutical
T-0128	DNA Topoisomerase I inhibitor[DDS drug camptothecin derivative] (Malignant tumor)	EU	Phase 1	Italy:Menarini
sTU-199 (Tenatoprazole)	Proton pump inhibitor (Gastroesophageal reflux disease)	EU	Phase 1	France:Negma (Sidem)
MP-412	Tyrosine kinase inhibitor (Malignant tumor)	US	Phase 1	US:AVEO Pharmaceuticals
TT-138	β 3 receptor agonist (Pollakiuria, Anischuria)	US	Phase 1	US:MediciNova

4. Changes Since Previous Announcement on October 30, 2008

Product name Development code (Generic name)	Category (Indications)	As of Oct 30, 2008	As of Jan. 29, 2009
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	Phase 2 in Japan	Phase 3 in Japan
Remicade (Infliximab(recombinant))	Anti-TNF α monoclonal antibody (Crohn's disease: dose escalation)	None	Phase 3 in Japan
Modiodal (Modafinil)	Psychoneurotic agent (Obstructive sleep apnea)	sNDA filed in Japan (May. 2008)	Phase 3 in Japan
TA-1790 (Avanafil)	PDE5 inhibitor (Erectile dysfunction)	Phase 2 Overseas (US:Vivus)	Phase 3 Overseas (US:Vivus)
MP-124	PARP inhibitor (Acute Ischemic Stroke)	None	Phase 1 Overseas
Neuart (Freeze-dried concentrated human antithrombin III)	Anticoagulant (Toxemia of Pregnancy)	sNDA filed in Japan (Dec.1995)	Deleted (sNDA file was withdrawn)