

State of New Product Development (as of July 30, 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
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 (Teneligliptin)	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 (Canagliflozin)	SGLT2 inhibitor (Diabetes mellitus)	Phase 1	In-house	

*: Orphan drug designated

(2) Additional Indications

Product name (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 scleroderma)	Phase 3		
	(Myasthenia gravis)	Phase 3		
Remicade (Infliximab(recombinant))	Anti-TNF α monoclonal antibody		US:Centocor	
	(Psoriasis)	sNDA filed (Feb. 2008)		
	(Ankylosing spondylitis*)	sNDA filed (Sep. 2008)		
	(Ulcerative colitis)	sNDA filed (June 2009)		
	(Crohn's disease: dose escalation)	Phase 3		
Pazucross (Pazufloxacin mesilate)	New quinolone antibacterial agent (Severe or intractable case: additional dose) (Sepsis, Pneumococcus)	sNDA filed (June 2009)	Japan: Toyama Chemical	Co-development -Toyama Chemical
Modiodal (Modafinil)	Psychoneurotic agent (Obstructive sleep apnea)	Phase 3	US:Cephalon	Co-development -Alfresa Pharma
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	
Cholebine (Colestimide(JAN))	Bile acid signal regulation (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)	US, Canada	Phase 2	Canada: Cytochroma	
MCI-186 (Edaravone)	Free radical scavenger (Acute Ischemic Stroke)	EU	Phase 2	In-house	
TA-5493	p38 inhibitor (Rheumatoid arthritis, Psoriasis)	EU	Phase 1	In-house	
MP-513 (Teneligliptin)	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	
MP-136	PPAR alpha agonist (Dyslipidemia)	EU	Phase 1	In-house	

(2) Additional Indications

Development code (Generic name)	Category (Indications)	Region	Stage	Origin	Remarks
MCI-9038 (Argatroban)	Thrombin inhibitor (HIT Patients undergoing percutaneous coronary intervention(PCI): additional dose)	EU	sNDA (May 2009)	In-house	
	(Heparin-induced thrombocytopenia (HIT))	EU	Preparing for sNDA		

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 3	Korea:Choongwae Pharma
T-0047 (Fingolimod)	Cell adhesion inhibitor [$\alpha4\beta7/\alpha4\beta1$ inhibitor] (Multiple sclerosis)	EU	Phase 2	UK:GlaxoSmithKline
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Diabetes mellitus, Obesity)	EU, US	Phase 2	US: Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
MKC-242	5-HT1A receptor agonist (Insomnia)	US	Phase 2	US:MediciNova
TA-2005 Carmoterol	Long-acting $\beta2$ agonist (Asthma, COPD)	EU	Phase 2	Italy:Chiesi Farmaceutici
MKC-231	Neurogenesis enhancer (Depression/Anxiety)	US	Phase 2	US:BrainCells
Y-39983	ROCK (rho-kinase) inhibitor (Glaucoma)	Japan	Phase 2	Japan: Senju Pharmaceutical
MT-210	5-HT2A/ Sigma 2 antagonist (Schizophrenia)	EU	Phase 2	France: Index/Cyrenaic
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	$\beta3$ receptor agonist (Pollakiuria, Anischuria)	US	Phase 1	US:MediciNova

4. Changes Since Previous Announcement on May 8, 2009

Product name Development code (Generic name)	Category (Indications)	As of May. 8, 2009	As of July 30, 2009
Valixa (Valganciclovir)	Antiviral (Post- transplantation cytomegalovirus infection)	sNDA filed (June 2008)	Approved (May, 2009)
Ceredist (Taltirelin hydrate)	Spinocerebellar degeneration remedy (Orally disintegrating tablet: additional formulation)	sNDA filed (July 2008)	Approved (June, 2009)
Remicade (Infliximab(recombinant))	Anti-TNF α monoclonal antibody (Rheumatoid arthritis: dose escalation) (Rheumatoid arthritis (including prevention of structural joint damage: additional indication)	sNDA filed (Sep. 2007)	Approved (July, 2009)
	(Ulcerative colitis)	Phase 3 in Japan	sNDA filed (June 2009)
Pazucross (Pazufloxacin mesilate)	New quinolone antibacterial agent (Severe or intractable case: additional dose) (Sepsis, Pneumococcus)	Phase 3 in Japan	sNDA filed (June 2009)
TA-1790 (Avanafil)	PDE5 inhibitor (Erectile dysfunction)	Phase 2 in Korea	Phase 3 in Korea
MCI-186 (Edaravone)	Free radical scavenger (Acute Ischemic Stroke)	Phase 1 in EU	Phase 2 in EU
MT-210	5-HT _{2A} / Sigma 2 antagonist (Schizophrenia)	None	Phase 2 in EU