(3) State of New Product Development (as of Jul 29, 2011)

i. Pipeline in Japan

New Molecular Entities

Development code (Generic name)	Category (Indications)	Stage	Origin	Remarks
FTY720 (Fingolimod)	Sphingosine-1-phosphate receptor modulator (Multiple sclerosis*)	NDA filed (Dec. 2010)	In-house	Co-development -Novartis Pharma K.K.
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	NDA filed (Jan. 2011)	US:Vertex	
MP-513 (Teneligliptin)	DPP4 Inhibitor (Type 2 Diabetes mellitus)	Phase 3	In-house	
BK-4SP	Vaccine (Prophylaxis of pertussis, diphtheria, tetanus, and poliomyelitis)	Phase 3	The Research Foundation for Microbial Diseases of Osaka University	Co-development -The Research Foundation for Microbial Diseases of Osaka University
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type 2 Diabetes mellitus)	Phase 3	In-house	
MP-214 (Cariprazine)	D3/D2 receptor antagonist (Schizophrenia)	Phase 2	Hungary: Gedeon-Richter	
MP-435	C5a receptor antagonist (Rheumatoid arthritis)	Phase 2	In-house	
MT-4666	α7nAChR agonist (Alzheimer's disease)	Phase 1	US: EnVivo Pharmaceuticals	

Additional Indications

Development code/Product Name (Generic name)	Category (Indications)	Stage	Origin	Remarks
Venoglobulin IH (Polyethylene glycol treated human normal immunogloblin)	Human immunoglobulin G (IgG2 deficiency)	sNDA filed (Dec. 1997)	In-house	
	(Systemic scleroderma)	Phase 3		
	(Myasthenia gravis*)	sNDA filed (Dec. 2010)		
Modiodal (Modafinil)	Psychoneurotic agent (Obstructive sleep apnea syndrome)	sNDA filed (May 2010)	US: Cephalon	Co-development -Alfresa Pharma
Remicade (Infliximab[recombinant])	Anti-TNFα monoclonal antibody (Crohn's disease*: dose escalation)	sNDA filed (Dec. 2010)	US: Janssen Biotech (ex-Centocor Ortho Biotech)	
Radicut (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	Phase 3	In-house	
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

ii. Pipelines Overseas

New Molecular Entities

Development code (Generic name)	Category (Indications)	Region	Stage	Origin	Remarks
LIVALO (Pitavastatin)	HMG-CoA reductase inhibitor (Primary hyperlipidemia and mixed dyslipidemia)	Indonesia	NDA filed (Jun. 2010)	Japan: Kowa	Filed by Tanabe Indonesia
MCI-196 (Colestilan(INN))	Non-absorbed phosphate binder (Hyperphosphatemia)	US, Europe	Phase 3	In-house	
MP-146	Uremic toxin adsorbent (Chronic kidney disease)	US, Europe	Phase 3	Japan:Kureha	
MT-2832 (Lunacalcipol)	Vitamin D analog (Secondary hyperparathyroidism)	US, Canada	Phase 2	Canada: Cytochroma	
MCI-186 (Edaravone)	Free radical scavenger (Acute ischemic stroke)	Europe	Phase 2	In-house	
MP-513 (Teneligliptin)	DPP4 inhibitor (Type 2 diabetes mellitus)	Europe US	Phase 2 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)	Europe	Phase 1	In-house	
MP-124	PARP inhibitor (Acute ischemic stroke)	US, Canada	Phase 1	In-house	
MP-136	PPAR alpha agonist (Dyslipidemia)	Europe	Phase 1	In-house	
MT-3995	Selective mineralocorticoid receptor antagonist (Hypertention)	Europe	Phase 1	In-house	
MP-157	Angiotensin Type2 Receptor agonist (Hypertention)	Europe	Phase 1	In-house	
MT-1303	Sphingosine-1-phosphate receptor modulator (Multiple sclerosis)	Europe	Phase 1	In-house	

iii. Licensing-out

Development code (Generic name)	Category (Indications)	Region	Stage	Licensee
TA-1790 (Avanafil)	PDE5 inhibitor (Erectile dysfunction)	Korea	Filed	Korea: JW Pharmaceutical
		US	Filed	US: Vivus
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type2 Diabetes mellitus)	US, Europe	Phase 3	US: Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
	(Obesity)	US, Europe	Phase 2	
T-0047 (Firategrast)	Cell adhesion inhibitor [α4β7/α4β1 inhibitor] (Multiple sclerosis)	Europe	Phase 2	UK:GlaxoSmithKline
MKC-242	5-HT1A receptor agonist (Insomnia)	US	Phase 2	US:MediciNova
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 receptor antagonist (Schizophrenia)	Europe	Phase 2	France: Cyrenaic
MKC-733	5-HT3 receptor agonist (Gastroesophageal reflux disease)	US	Phase 2	US: Edusa Pharmaceuticals
sTU-199 (Tenatoprazole)	Proton pump inhibitor (Gastroesophageal reflux disease)	Europe	Phase1	France:Negma (Sidem)
TT-138	β3 receptor agonist (Pollakiuria, urinary incontinence)	US	Phase 1	US:MediciNova
TA-7906	PDE4 inhibitor (Atopic dermatitis)	Japan	Phase1	Japan: Maruho

iv. Changes Since Previous Announcement on May 10, 2011

Own Development

Development code (Generic name)	Category (Indications)	As of May. 10, 2011	As of Jul 29, 2011
CNTO148 (Golimumab)	Anti-TNFα monoclonal antibody (Rheumatoid arthritis)	NDA filed in Japan (Jun. 2010)	Approved in Japan (Jul. 2011)
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type 2 Diabetes mellitus)	Phase 2 in Japan	Phase 3 in Japan
MCI-9038 (Argatroban)	Thrombin inhibitor (Prevention of the blood clottingcoagulation in under dialysis and percutaneous coronary intervention in patients with heparin-induced thrombocytopenia [HIT] type II*1)	sNDA filed in Japan (Aug. 2010)	Approved in Japan (May 2011)
Maintate (Bisoprolol)	Selective β1 antagonist (Chronic heart failure)	sNDA filed in Japan*2 (Nov. 2010)	Approved in Japan (May 2011)
AZANIN (Azathioprine)	Immunosuppressant (Systemic vasculitis, systemic lupus erythematosus, polymyositis[SLE], dermatomyositis, scleroderma, mixed connective tissue disease, intractable rheumatic disease)	sNDA filed in Japan*2 (Nov. 2010)	Approved in Japan (May 2011)
Anti-D Human Immunogloblin	Anti-D Human Immunogloblin (Suppression of immunization of the D(Rho) factor [post partum, treatment through pregnancy or for parturition, abdominal bruise etc., and pregnancy around 28 weeks])	sNDA filed in Japan*2 (Nov. 2010)	Approved in Japan (May 2011)
LIVALO (Pitavastatin)	HMG-CoA reductase inhibitor (Primary hypercholesterolemia and mixed dyslipidemia)	NDA filed in Taiwan (Apr. 2010)	Approved in Taiwan (Jan. 2011)

*1: Orphan drug designated

*2: Filed based on the said published evidence

Licensing-out

Development code (Generic name)	Category (Indications)	As of May 10, 2011	As of Jul. 29, 2011
TA-1790 (Avanafil)	PDE5 inhibitor (Erectile dysfunction)	Phase 3 in US	NDA Filed in US (Jun. 2011)