

(2) State of New Product Development (As of Jan. 31, 2012)

i. Pipeline in Japan
New Molecular Entities

Development code (Generic name)	Category (Indications)	Stage	Origin	Notes
MP-513 (Teneligliptin)	DPP4 Inhibitor (Type 2 Diabetes mellitus)	NDA filed (Aug. 2011)	In-house	
	(Type 2 Diabetes mellitus, Additional combination)	Phase3		
BK-4SP	Vaccine (Prophylaxis of pertussis, diphtheria, tetanus, and poliomyelitis)	NDA filed (Dec. 2011)	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 partial agonist (Schizophrenia)	Phase 2	Hungary: Gedeon-Richter	
MP-435	C5a receptor antagonist (Rheumatoid arthritis)	Phase 2	In-house	
MT-4666	α 7nAChR agonist (Alzheimer's disease)	Phase 1	US: EnVivo Pharmaceuticals	

Additional Indications

Product name (Generic name)	Category (Indications)	Stage	Origin	Notes
Venoglobulin IH (Polyethylene glycol treated human normal immunoglobulin)	Human immunoglobulin G (IgG2 deficiency)	sNDA filed (Dec. 1997)	In-house	
	(Systemic scleroderma)	Phase 3		
Radicut (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	Phase 3	In-house	
Maintate (Bisoprolol)	Selective β 1 blocker (Chronic atrial fibrillation)	Phase 3	In-house	
Talion (Bepotastine)	Selective histamine H1 receptor antagonist· anti-allergic agent (Pediatric allergic rhinitis)	Phase 3	Japan: Ube Industries	
Telavic (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C, (genotype2))	Phase 3	US:Vertex	
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. Pipeline Overseas

New Molecular Entities

Development code (Generic name)	Category (Indications)	Region	Stage	Origin	Notes
MCI-196 (Colestilan(INN))	Non-absorbed phosphate binder (Hyperphosphatemia)	Europe	MAA filed (Aug. 2011)	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	Phase 2	In-house	
		US	Phase 1		
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 functiona antagonist (Multiple sclerosis)	Europe	Phase 1	In-house	
MT-7716	NOP receptor agonist (Alcohol-use disorder)	US	Phase 1	In-house	

iii. Licensing-out

Development code (Generic name)	Category (Indications)	Region	Stage	Licensee
TA-1790 (Avanafil)	PDE5 inhibitor (Erectile dysfunction)	US	NDA Filed (Jun. 2011)	US: Vivus
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type2 Diabetes mellitus)	US, Europe	Phase 3	US: Janssen Pharmaceuticals*
	(Obesity)	US, Europe	Phase 2	
T-0047 (Firategrast)	Cell adhesion inhibitor [$\alpha4\beta7/\alpha4\beta1$ 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
sTU-199 (Tenatoprazole)	Proton pump inhibitor (Gastroesophageal reflux disease)	Europe	Phase1	France:Negma (Sidem)
TT-138	$\beta3$ receptor agonist (Pollakiuria, urinary incontinence)	US	Phase 1	US:MediciNova
TA-7906	PDE4 inhibitor (Atopic dermatitis)	Japan	Phase1	Japan: Maruho

*: A pharmaceutical company of Johnson & Johnson

iv. Changes Since Previous Announcement on Oct 31, 2011
In-house Development

Development code/Product name (Generic name)	Category (Indications)	Region	As of Oct. 31, 2011	As of Jan 31, 2012
Modiodal (Modafinil)	Psychoneurotic agent (Obstructive sleep apnea syndrome)	Japan	sNDA filed (May 2010)	Approved (Nov. 2011)
Livalo (Pitavastatin)	HMG-CoA reductase inhibitor (Primary hyperlipidemia, mixed dyslipidemia)	Indonesia	NDA filed (Jun. 2010)	Approved (Nov. 2011)
BK-4SP	Vaccine (Prophylaxis of pertussis, diphtheria, tetanus, and poliomyelitis)	Japan	Phase 3	NDA filed (Dec. 2011)
Telavic (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C, (genotype2))	Japan	None	Phase 3

Licensing-out

Development code (Generic name)	Category (Indications)		As of Jul 29, 2011	As of Jan 31, 2012
MKC-733	5-HT3 receptor agonist (Gastroesophageal reflux disease)	US	Phase 2	Termination of License Agreement