

(2) State of New Product Development (As of Feb. 1, 2013)

1. Pipeline in Japan

New Molecular Entities

Development code (Generic name)	Category (Indications)	Stage	Origin
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type 2 diabetes mellitus)	Phase 3	In-house
MP-214 (Cariprazine)	D3/D2 receptor partial agonist (Schizophrenia)	Phase 2b/3	Hungary: Gedeon-Richter
MP-435	C5a receptor antagonist (Rheumatoid arthritis)	Phase 2	In-house
MT-4666	$\alpha 7nACh$ receptor agonist (Alzheimer's disease)	Phase 2	US: EnVivo
MT-3995	Selective mineralocorticoid receptor antagonist (Hypertention)	Phase 1	In-house
MT-1303	Sphingosine-1-phosphate receptor functional antagonist (Multiple sclerosis)	Phase 1	In-house

Additional Indications

Product name (Generic name)	Category (Indications)	Stage	Origin
Omeprazon (Omeprazole)	Proton pump inhibitor (<i>Helicobacter pylori</i> eradication by concomitant therapy for <i>Helicobacter pylori</i> gastritis)	sNDA filed	UK:AstraZeneca
Maintate (Bisoprolol)	Selective β 1 blocker (Chronic atrial fibrillation)	sNDA filed	Switzerland: Merck Serono
Grtpa (Alteplase[recombinant])	Thrombolytic agent (Acute ischemic cerebrovascular disease [up to 4.5 hours after the onset of symptoms])	sNDA filed	US:Genentech
Radicut (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	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
Tenelia (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus, additional combination)	Phase 3	In-house
Remicade (Infliximab [recombinant])	Anti- human TNF α monoclonal antibody (Refractory Kawasaki disease*)	Phase 3	US:Janssen Biotech
	(Behcet's disease with special lesions*)	Phase 3	
	(Pediatric Crohn's disease)	Phase 3	
	(Pediatric ulcerative colitis)	Phase 3	
	(Psoriasis: increased dose)	Phase 3	
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. Pipelines Overseas

New Molecular Entities

Development code (Generic name)	Category (Indications)	Region	Stage	Origin
MP-146	Uremic toxin adsorbent (Chronic kidney disease)	US, Europe	Phase 3	Japan:Kureha
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	Taiwan	Filed	US:Vertex
MT-9938 (Nalfurafine)	κ -opioid receptor agonist (Refractory pruritus)	US	Phase 2	Japan:Toray
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Europe	Phase 2	In-house
		US	Phase 1	
GB-1057 (Recombinant human serum albumin)	Recombinant human serum albumin (Stabilizing agent)	US	Phase 1	In-house
MP-124	PARP inhibitor (Acute ischemic stroke)	US, Canada	Phase 1	In-house
MT-3995	Selective mineralocorticoid receptor antagonist (Hypertention)	Europe	Phase 1	In-house
MP-157	Angiotensin Type 2 receptor agonist (Hypertention)	Europe	Phase 1	In-house
MT-1303	Sphingosine-1-phosphate receptor functional antagonist (Multiple sclerosis)	Europe	Phase 1	In-house
MT-7716	NOP receptor agonist (Alcohol-use disorder)	US	Phase 1	In-house

3. Licensing-out

Development code (Generic name)	Category (Indications)	Region	Stage	Licensee
TA-1790 (Avanafil)	PDE5 inhibitor (Erectile dysfunction)	Europe	MAA filed (Mar. 2012)	US: Vivus
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type2 diabetes mellitus)	US	NDA filed (May 2012)	US: Janssen Pharmaceuticals
		Europe	MAA filed (Jun. 2012)	
	(Obesity)	US, Europe	Phase 2	
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Korea	Phase 3	Korea: Handok Pharmaceuticals
T-0047 (Finategrast)	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
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
TA-7906	PDE4 inhibitor (Atopic dermatitis)	Japan	Phase 2	Japan: Maruho
MCC-847	Leukotriene D4 receptor antagonist (Asthma)	Korea	Phase 2	Korea: SAMA Pharma
sTU-199 (Tenatoprazole)	Proton pump inhibitor (Gastroesophageal reflux disease)	Europe	Phase 1	France: Negma (Sidem)
TT-138	$\beta3$ receptor agonist (Pollakiuria, urinary incontinence)	US	Phase 1	US: MediciNova
MT-4580	Ca sensing receptor agonist (Secondary hyperparathyroidism)	Japan	Phase 1	Japan: Kyowa Hakko Kirin
Wf-516	SSRI / 5HT1A receptor antagonists (Depression)	Europe	Phase 1	US: SONKEI Pharmaceuticals

4. Changes Since Previous Announcement on Oct. 29, 2012

In-house Development

Development code/Product name (Generic name)	Category (Indications)	Region	As of October 29, 2012	As of February 1, 2013
MCI-196/BindRen (Colestilan[INN])	Non-absorbed phosphate binder (Hyperphosphatemia)	Europe	MAA filed (Aug. 2011)	Approved (January, 2013)
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	Taiwan	None	Filed (January, 2013)
MT-9938 (Nalfurafine)	κ -opioid receptor agonist (Refractory pruritus)	US	None	Phase 2
MT-4666	$\alpha 7nACh$ receptor agonist (Alzheimer's disease)	Japan	Phase 1	Phase 2

Licensing-out

Development code (Generic name)	Category (Indications)	Region	As of October 29, 2012	As of February 1, 2013
MCC-847	Leukotriene D4 receptor antagonist (Asthma)	Korea	None	Phase 2
MT-4580	Ca sensing receptor agonist (Secondary Hyperparathyroidism)	Japan	None	Phase 1
Wf-516	SSRI / 5HT1A receptor antagonists (Depression)	Europe	None	Phase 1