(2) State of New Product Development (As of July 31, 2013)

i. Pipeline in Japan

New Molecular Entities

Development code (Generic name)	Category (Indications)	Stage	Origin	Notes
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type 2 diabetes mellitus)	NDA filed (May 2013)	In-house	
MP-214 (Cariprazine)	D3/D2 receptor partial agonist (Schizophrenia)	Phase 2b/3	Hungary: Gedeon Richter	
MT-4666	α7nACh receptor agonist (Dementia of Alzheimer's type)	Phase 2	US: EnVivo	
MT-3995	Selective mineralocorticoid receptor antagonist (Hypertention)	Phase 1	In-house	
MT-1303	S1P receptor functional antagonist (Multiple sclerosis)	Phase 1	In-house	

Additional Indications

Product name (Generic name)	Category (Indications)	Stage	Origin	Notes
Tenelia (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus, additional combination)	sNDA filed (Feb. 2013)	In-house	
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	
	(Pediatric atopic dermatitis)	Phase 3		
Telavic (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C, [genotype2])	Phase 3	US:Vertex	
	(Chronic hepatitis C, [combination with Pegasys])	Phase 3		
	(Chronic hepatitis C, [combination with Feron])	Phase 3		
Remicade (Infliximab [recombinant])	Anti-human TNFα 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		
Imusera (Fingolimod)	S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)	Phase 3	In-house	Co-developed with Novartis Pharma, Multinational study
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
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	Taiwan	Filed (Jan. 2013)	US:Vertex
		Korea	Phase 1	
MP-146	Uremic toxin adsorbent (Chronic kidney disease)	US, Europe	Phase 3	Japan:Kureha
MT-9938 (Nalfurafine)	κ-opioid receptor agonist (Refractory pruritus in hemodialysis)	US,Canada	Phase 2	Japan:Toray
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Europe	Phase 2	In-house
		US	Phase 1	
MT-3995	Selective mineralocorticoid receptor antagonist (Diabetic nephropathy)	Europe	Phase 2	In-house
MT-1303	S1P receptor functional antagonist (Multiple sclerosis)	Europe	Phase 2	In-house
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
MP-157	Angiotensin Type 2 receptor agonist (Hypertention)	Europe	Phase 1	In-house

Additional Indications

Development code/Product name (Generic name)	Category (Indications)	Region	Stage	Origin
MCI-196/BindRen Colestilan[INN]	Non-absorbed phosphate binder (Pediatric hyperphosphatemia)	Europe	Phase 3	In-house

iii. Licensing-out

Development code (Generic name)	Category (Indications)	Region	Stage	Licensee (Notes)
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type2 diabetes mellitus)	Europe	MAA filed (Jul. 2012*1)	US: Janssen Pharmaceuticals
	(Type2 diabetes mellitus / fixed dose combination with metformin, IR*2)	US	NDA filed (Feb. 2013*1)	
	(Type2 diabetes mellitus / fixed dose combination with metformin, IR*2)	Europe	MAA filed (Mar. 2013)	
	(Obesity)	US, Europe	Phase 2	
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Korea	Phase 3	Korea: Handok Pharmaceuticals
FTY720 (Fingolimod)	S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)	Multinational study	Phase 3	Switzerland: Novartis (Co-developed with Novartis Pharma in Japan)
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
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	β3 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
Y-803	Bromodomain inhibitor (Hematological cancer)	US, Europe	Phase 1	Switzerland: OncoEthix (Development code: OTX015)

*1 Revised to the month when the application was accepted

*2 Immediate release

iv. Changes Since Previous Announcement on May 8, 2013

In-house Development

Development code/Product name (Generic name)	Category (Indications)	Region	As of May 8, 2013	As of July 31, 2013
Maintate (Bisoprolol)	Selective β1 blocker (Atrial fibrillation (tachycardiac))	Japan	sNDA filed (Sep. 2012)	Approved (Jun. 2013)
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type 2 diabetes mellitus)	Japan	Phase 3	NDA filed (May 2013)
MCI-196/BindRen Colestilan[INN]	Non-absorbed phosphate binder (Pediatric hyperphosphatemia)	Europe	None	Phase 3

Licensing-out

Development code (Generic name)	Category (Indications)	Region	As of May 8, 2013	As of July 31, 2013
TA-1790 (Avanafil)	PDE5 inhibitor (Erectile dysfunction)	Europe	MAA filed (Mar. 2012)	Approved (Jun. 2013)