(2) State of New Product Development (As of February 3, 2014)

i. New Drugs

Development code (Generic name)	Category (Indications)	Region	Stage	Origin
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type 2 diabetes mellitus)	Japan	Filed (May, 2013)	In-house
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	Taiwan	Filed (Jan., 2013)	US:Vertex
		Korea	Phase 1	
MT-4666	α7nACh receptor agonist (Dementia of Alzheimer's type)	Multinational study	Phase 3	US: EnVivo
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist (Schizophrenia)	Japan	Phase 2b/3	Hungary: Gedeon Richter
MT-9938 (Nalfurafine)	κ-opioid receptor agonist (Refractory pruritus in Hemodialysis patients)	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
		Japan	Phase 2	
MT-1303	S1P receptor functional antagonist (Multiple sclerosis)	Europe	Phase 2	In-house
		Japan	Phase 1	
	(Psoriasis)	Europe	Phase 2	
	(Inflammatory bowel disease)	Europe	Phase1	
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of H5N1 influenza)	Canada	Phase 2	In-house (Canada:Medicago)
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of seasonal influenza)	US	Phase 1/2	In-house (Canada:Medicago)
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 (Hypertension)	Europe	Phase 1	In-house

ii. Additional Indications

Product name (Generic name)	Category (Indications)	Region	Stage	Origin	Notes
Telavic (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C, [genotype2])	Japan	sNDA filed (Dec., 2013)	US:Vertex	
	(Chronic hepatitis C, [combination with Pegasys])		Phase 3		
	(Chronic hepatitis C, [combination with Feron])		Phase 3		
Radicut (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	Japan	Phase 3	In-house	
Talion (Bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent (Pediatric allergic rhinitis)	Japan	Phase 3	Japan: Ube Industries	
	(Pediatric atopic dermatitis)		Phase 3		
Remicade (Infliximab [recombinant])	Anti-human TNFα monoclonal antibody (Refractory Kawasaki disease*)	Japan	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)	Multinational study	Phase 3	In-house	with Novartis Pharma in Japan, licensed to Novartis overseas
BindRen (Colestilan[INN])	Non-absorbed phosphate binder (Pediatric hyperphosphatemia)	Europe	Phase 3	In-house	
Cholebine (Colestimide[JAN])	Bile acid signal regulation (Type 2 diabetes mellitus)	Japan	Phase 2	In-house	
	Non-absorbed phosphate binder (Hyperphosphatemia)		Phase 1		

* Orphan drug designated

iii. Licensing-out

Development code (Generic name)	Category (Indications)	Region	Stage	Licensee (Notes)
TA-7284 (Canagloflozin)	SGLT2 inhibitor (Type2 diabetes mellitus / fixed dose combination with metformin, IR)	US	FDA Complete Response (Dec., 2013)	US: Janssen Pharmaceuticals
		Europe	MAA filed (Mar., 2013)	
	(Obesity)	US, Europe	Phase 2	
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Korea	NDA filed (Sep., 2013)	Korea: Handok
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	US:Minerva Neuroscience *
TA-7906	PDE4 inhibitor (Atopic dermatitis)	Japan	Phase 2	Japan: Maruho
MCC-847	Leukotriene D4 receptor antagonist (Asthma)	Korea	Phase 2	Korea: SAMA Pharma
TA-8995	CETP inhibitor (Dyslipidemia)	Netherlands, Danmark	Phase 2	Netherlands: DEZIMA Pharma
MT-4580	Ca sensing receptor agonist (Secondary hyperparathyroidism in hemodialysis patients)	Japan	Phase 1/2	Japan: Kyowa Hakko Kirin
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
Wf-516	SSRI / 5HT1A receptor antagonists (Depression)	Europe	Phase 1	US:Minerva Neuroscience *
Y-803	Bromodomain inhibitor (Hematological cancer)	US, Europe	Phase 1	Switzerland: OncoEthix (Development code: OTX015)

* : New company established by the marger of Cyrenaic and SONKEI Pharmaceuticals in November, 2013

iv. Changes Since Previous Announcement on October 30, 2013

In-house Development

Development code/Product name (Generic name)	Category (Indications)	Region	As of October 30, 2013	As of February 3, 2014
Tenelia (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus, additional combination)	Japan	sNDA filed (Feb., 2013)	Approved (Dec., 2013)
Telavic (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C, [genotype2])	Japan	Phase 3	sNDA filed (Dec., 2013)
MT-4666	α7nACh receptor agonist (Dementia of Alzheimer's type)	Multinational study	Phase 2	Phase 3
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of H5N1 influenza)	Canada	None	Phase 2
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of seasonal influenza)	US	None	Phase 1/2

Licensing-out

Development code (Generic name)	Category (Indications)	Region	As of October 30, 2013	As of February 3, 2014
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type2 diabetes mellitus)	Europe	MAA filed (Jun. 2012*)	Approved (Nov., 2013)
	(Type2 diabetes mellitus / fixed dose combination with metformin, IR)	US	NDA filed (Dec. 2012*)	FDA Complete Response (Dec., 2013)
TA-8995	CETP inhibitor (dyslipidemia)	Netherlands, Danmark	None	Phase 2

*: The month when the application was filed