(2) State of New Product Development (As of July 31, 2015)

i. New Drugs

Development code (Generic name)	Category (Indications)	Region	Stage	Origin
TA-650 (infliximab)	Anti-human TNFα monoclonal antibody (Crohn's disease, ulcerative colitis, pediatric Crohn's disease, pediatric ulcerative colitis)	Taiwan	Filed (Sep., 2013)	US:Janssen Biotech
TA-7284 (canagliflozin)	SGLT2 inhibitor (Type 2 diabetes mellitus)	Taiwan	Filed (Mar., 2015)	In-house
MP-513 (teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Indonesia	Filed (Apr., 2015)	In-house
		Europe	Phase 2	
		US	Phase 1	
MCI-186 (edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*1)	Korea	Filed (Jun., 2015)	In-house
MT-4666 (encenicline)	α7nACh receptor agonist (Dementia of Alzheimer's type)	Global clinical trial*2	Phase 3	US: FORUM Pharmaceuticals
MT-2412 (teneligliptin, canagliflozin)	Fixed-dose combination of DPP-4 inhibitor and SGLT2 inhibitor (Type 2 diabetes mellitus)	Japan	Phase 3	In-house
MP-214 (cariprazine)	Dopamine D3/D2 receptor partial agonist (Schizophrenia)	Japan,Asia	Phase 2b/3	Hungary: Gedeon Richter
MT-3995	Selective mineralocorticoid receptor antagonist (Diabetic nephropathy)	Europe	Phase 2	In-house
		Japan	Phase 2	
		US	Phase 1	
MT-1303	S1P receptor functional antagonist (Multiple sclerosis)	Europe	Phase 2	In-house
	(Psoriasis)	Europe	Phase 2	
	(Crohn's disease)	Japan,Europe	Phase 2	
	(Inflammatory diseases, autoimmune diseases)	Japan,Europe, US	Phase1	
MT-2301	Haemophilus influenza type b (Hib) vaccine (Prophylaxis of pediatric Hib infection)	Japan	Phase 2	US: Nuron Biotech
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of H5N1 influenza)	Canada	Phase 2	In-house
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of seasonal influenza)	US, Canada	Phase 2	In-house
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of H7N9 influenza)	Canada	Phase 1	In-house
GB-1057 (Recombinant human serum albumin)	Blood and Blood forming organs	US	Phase 1	In-house
MP-124	Nervous system	US	Phase 1	In-house
MP-157	Cardiovascular system	Europe	Phase 1	In-house
MT-0814	Ophthalmologicals	Japan	Phase 1	In-house
MT-8554	Nervous system etc.	Europe	Phase 1	In-house

*1:Orphan drug designated

*2:Co-developed with FORUM Pharmaceuticals.

ii. Additional Indications

Product name (Generic name)	Category (Indications)	Region	Stage	Origin	Notes
Remicade (infliximab)	Anti-human TNFα monoclonal antibody (Behcet's disease with special lesions*)	Japan	sNDA filed (Oct., 2014)	US:Janssen Biotech	
	(Refractory Kawasaki disease*)		sNDA filed (May, 2015)		
	(Pediatric Crohn's disease)		Phase 3		
	(Pediatric ulcerative colitis)		Phase 3		
	(Psoriasis: increased dose)		sNDA filed (Jul., 2015)		
Tribik (Adsorbed Diphtheria-purified Pertussis-tetanus Combined Vaccine)	Vaccine (Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)	Japan	sNDA filed (Apr., 2015)	Japan:The Research Foundation for Microbial Diseases of Osaka University	Co-developed with The Research Foundation for Microbial Diseases of Osaka University
Telavic (telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C, [combination with Feron])	Japan	Phase 3	US:Vertex Pharmaceuticals	
Imusera (fingolimod)	S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)	Global clinical trial	Phase 3	In-house	Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas
Canaglu (canagliflozin)	SGLT2 inhibitor (Diabetic nephropathy)	Global clinical trial	Phase 3	In-house	Sponsor: Janssen Research & Development, LLC

*Orphan drug designated

iii. Licensing-out

Development code (Generic name)	Category (Indications)	Region	Stage	Licensee (Notes)
TA-7284 (canagliflozin)	SGLT2 inhibitor (Type2 diabetes mellitus / fixed dose combination with metformin, XR)	US	Phase 3	US: Janssen Pharmaceuticals, Inc
	(Diabetic nephropathy)	Global clinical trial	Phase 3	
	(Type 1 Diabetes Mellitus)	US, Canada	Phase 2	
	(Obesity / co-administration with phentermine)	US	Phase 2	
FTY720 (fingolimod)	S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)	Global clinical trial	Phase 3	Switzerland: Novartis (Co-developed with Novartis Pharma in Japan)
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 Neurosciences
TA-7906	PDE4 inhibitor (Atopic dermatitis)	Japan	Phase 2	Japan: Maruho
MCC-847 (masilukast)	Leukotriene D4 receptor antagonist (Asthma)	Korea	Phase 2	Korea: SAMA Pharma
TA-8995	CETP inhibitor (Dyslipidemia)	Europe	Phase 2	Netherlands: DEZIMA Pharma
MT-4580	Ca sensing receptor agonist (Secondary hyperparathyroidism in hemodialysis patients)	Japan	Phase 2	Japan: Kyowa Hakko Kirin
Wf-516	Multiple mechanisms on several receptors* (Depression)	Europe	Phase 2	US: Minerva Neurosciences
Y-803	Bromodomain inhibitor (Cancer)	Europe, Canada	Phase 2	US: Merck
sTU-199 (tenatoprazole)	Alimentary tract and metabolism	Europe	Phase 1	France: Negma/Sidem

*SSRI, 5-HT1A, dopamine transporter, and alpha-1A and B

iv. Changes Since Previous Announcement on May 8, 2015

In-house Development

Development code/ product name (Generic name)	Category (Indications)	Region	As of May 8, 2015	As of July 31, 2015
Talion (bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent (Pediatric allergic rhinitis)	Japan	sNDA filed (May, 2014)	Approved (May, 2015)
	(Pediatric urticaria and pruritus accompanying dermatitis [eczema or skin inflammation, itching])		sNDA filed (May, 2014)	Approved (May, 2015)
Radicut (edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	Japan	sNDA filed (Oct., 2014)	Approved (Jun., 2015)
MCI-186 (edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	Korea	None	Filed (Jun., 2015)
Remicade (infliximab)	Anti-human TNFα monoclonal antibody (Refractory Kawasaki disease*)	Japan	Phase 3	sNDA filed (May, 2015)
	(Psoriasis: increased dose)		Phase 3	sNDA filed (Jul., 2015)
MT-1303	S1P receptor functional antagonist (Crohn's disease)	Japan,Europe	None	Phase 2
MT-8554	Nervous system etc.	Europe	None	Phase 1

*Orphan drug designated

Licensing-out

Development code (Generic name)	Category (Indications)	Region	As of May 8, 2015	As of July 31, 2015
TA-7284 (canagliflozin)	SGLT2 inhibitor (Type 1 Diabetes Mellitus)	US, Canada	None	Phase 2
	(Obesity / co-administration with phentermine)	US	None	Phase 2
Wf-516	Multiple mechanisms on several receptors* (Depression)	Europe	Phase 1	Phase 2
Y-803	Bromodomain inhibitor (Cancer)	Europe, Canada	Phase 1	Phase 2

*SSRI, 5-HT1A, dopamine transporter, and alpha-1A and B