

(2) State of New Product Development (as of August 2, 2016)

i. New Drugs

Development code (Generic name)	Category (Indications)	Region	Stage	Origin
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	
TAU-284 (bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent (Pediatric allergic rhinitis, Pediatric atopic dermatitis)	China	Filed (Mar., 2016)	Japan: Ube Industries
MCI-186 (edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis)	US	NDA filed (June, 2016)	In-house
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 (amiselimod)	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	Phase 1	
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
MT-5199	Nervous system	Japan	Phase 1	US:Neurocrine Biosciences
MT-7117	Dermatologicals, etc. (Inflammatory diseases, autoimmune diseases, etc.)	Europe	Phase 1	In house

ii. Additional Indications & Administration

Product name (Generic name)	Category (Indications)	Region	Stage	Origin	Notes
Remicade (infliximab)	Anti-human TNF α monoclonal antibody (Pediatric Crohn's disease)	Japan	Phase 3	US:Janssen Biotech	
	(Pediatric ulcerative colitis)		Phase 3		
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

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	NDA filed (Nov., 2015)	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)
MT-4580	Ca sensing receptor agonist (Secondary hyperparathyroidism in hemodialysis patients)	Japan	Phase 3	Japan: Kyowa Hakko Kirin
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
MCC-847 (masilukast)	Leukotriene D4 receptor antagonist (Asthma)	Korea	Phase 2	Korea: SAMA Pharma
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 11, 2016

New drugs

Development code (Generic name)	Category (Indications)	Region	As of May 11, 2016	As of Aug. 2, 2016	Origin (Notes)
MCI-186 (edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis)	US	None	NDA filed (June, 2016)	In-house
MT-7117	Dermatologicals, etc. (Inflammatory diseases, autoimmune diseases, etc.)	Europe	None	Phase 1	In-house
MT-4666	$\alpha 7$ nACh receptor agonist (Dementia of Alzheimer's type)	Japan	Phase 2	Deleted	(Cancellation of license agreement with FORUM Pharmaceuticals)

Additional Indications & Administration

Product name (Generic name)	Category (Indications)	Region	As of May 11, 2016	As of Aug. 2, 2016	Origin
Remicade (infliximab)	Anti-human TNF α monoclonal antibody (Psoriasis: increased dose)	Japan	sNDA filed (Jul., 2015)	Approved (May, 2016)	Janssen Biotech