

(2) State of New Product Development (as of January 31, 2019)

i. Autoimmune diseases

Development code Product name (Generic name)	Category (Indications)	Region Stage	Origin/licensee
Azanin (Azathioprine)	Immunosuppressant (Autoimmune hepatitis)	Japan Filed (Aug. 2018)	Licensed from GlaxoSmithKline (UK)
MT-5547 (Fasimumab)	Fully human anti-NGF monoclonal antibody (Osteoarthritis)	Japan Phase 2/3	Licensed from Regeneron (US)
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	
MT-7117	Dermatologicals, etc. (Erythropoietic protoporphyria)	US Phase 2	In-house
MT-2990	Inflammatory diseases, autoimmune diseases, etc.	Phase 1	In-house

ii. Diabetes and kidney diseases

Development code Product name (Generic name)	Category (Indications)	Region Stage	Origin/licensee
TA-7284 Canaglu/INVOKANA (Canagliflozin)	SGLT2 inhibitor (Type 2 diabetes mellitus)	Indonesia Filed (Aug. 2017)	In-house
	(Diabetic nephropathy)	Japan, US, Europe, and others Phase 3 (Global clinical trial)	Discovered in-house Sponsor: Janssen Research & Development (US)
MP-513 Tenelia (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Indonesia Filed (Apr. 2015)	In-house
		Singapore Filed (Jul. 2018)	
		Thailand Filed (Sep. 2018)	
		Malaysia Filed (Dec. 2018)	
		China Phase 3	
		Europe Phase 2	
MT-6548 (Vadadustat)	Hypoxia inducible factor prolyl hydroxylase inhibitor (Renal anemia)	Japan Phase 3	Licensed from Akebia (US)
MT-3995 (Apararenone)	Selective mineralocorticoid receptor antagonist (Diabetic nephropathy)	Europe Phase 2	In-house
		Japan Phase 2	
	(Non-alcoholic steatohepatitis: NASH)	Japan Phase 2	

iii. Central nervous system diseases

Development code Product name (Generic name)	Category (Indications)	Region Stage	Origin/licensee
MCI-186 Radicut/Radicava (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis: ALS)	Switzerland Filed (Dec. 2017)	In-house
		Europe Filed (May 2018)	
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist (Schizophrenia)	Singapore Filed (Jun. 2018)	Licensed from Gedeon Richter (Hungary)
		Thailand Filed (Aug. 2018)	
		Indonesia Filed (Dec. 2018)	
MT-210 (Roluperidone)	5-HT2A/Sigma 2 receptor antagonist (Schizophrenia)	US, Europe Phase 3	Licensed to Minerva Neurosciences (US)
MT-5199 (Valbenazine)	Vesicular monoamine transporter type 2 inhibitor (Tardive dyskinesia)	Japan Phase 2/3	Licensed from Neurocrine Biosciences (US)
Wf-516	Multiple mechanisms on several receptors* (Major depressive disorder)	US, Europe Phase 2	Licensed to Minerva Neurosciences (US)
MT-8554	Nervous system, etc. (Painful diabetic peripheral neuropathy)	Europe Phase 2	In-house
	(Vasomotor symptoms associated with menopause)	US Phase 2	
ND0612 (Levodopa/Carbidopa)	Continuous SC pump/patch pump (Parkinson's disease)	US, Europe Phase 2	In-house
MP-124	Nervous system	Phase 1	In-house
ND0701 (Apomorphine)	Continuous SC pump (Parkinson's disease)	Phase 1	In-house
MT-1186 (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis: ALS / Oral suspension)	Phase 1	In-house
MT-6345	Nervous system	Phase 1	Co-developed with Ube Industries (Japan)

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

iv. Vaccines

Development code	Category (Indications)	Region Stage	Origin/licensee
MT-2355	Combined vaccine (Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants)	Japan Phase 3	Co-developed with The Research Foundation for Microbial Diseases of Osaka University (Japan)
MT-2271	Plant-based VLP vaccine (Prophylaxis of seasonal influenza/adults)	US, Europe, Canada, and others Phase 3	Medicago product (Canada)
	(Prophylaxis of seasonal influenza/elderly)	US, Europe, Canada, and others Phase 3	
MT-8972	Plant-based VLP vaccine (Prophylaxis of H5N1 influenza)	Canada Phase 2	Medicago product (Canada)
MT-7529	Plant-based VLP vaccine (Prophylaxis of H7N9 influenza)	Phase 1	Medicago product (Canada)
MT-5625	Plant-based VLP vaccine (Prophylaxis of rotavirus gastroenteritis)	Phase 1	Medicago product (Canada)

v. Other diseases

Development code Product name (Generic name)	Category (Indications)	Region Stage	Origin/licensee
TAU-284 Talion (Bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent (Allergic rhinitis, Urticaria)	Thailand Filed (Nov. 2018)	Licensed from Ube Industries (Japan)
MT-4580 Orkedia (Evocalcet)	Ca sensing receptor agonist (Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism)	Japan Phase 3	Licensed to Kyowa Hakko Kirin (Japan)
MCC-847 (Masilukast)	Leukotriene D4 receptor antagonist (Asthma)	Korea Phase 2	Licensed to SAMA Pharma (Korea)
Y-803	Bromodomain inhibitor (Cancer)	Europe, Canada Phase 2	Licensed to Merck (US)
MT-0814	Ophthalmologicals	Phase 1	In-house
MT-4129	Cardiovascular system, etc.	Phase 1	In-house

Changes Since Previous Announcement

Development code Product name (Generic name)	Category (Indications)	Previous Announcement	As of Jan 31, 2019	Origin / licensee
TA-7284 Canaglu/ INVOKANA (Canagliflozin)	SGLT2 inhibitor (Reduce the composite risk of CV death, MI or stroke in type 2 diabetes with established cardiovascular disease (CANVAS /CANVAS-R))	US Filed (Sep. 2017)	US Approved (Oct. 2018)	Licensed to Janssen Pharmaceuticals (US)
FTY720 Imusera/Gilenya (Fingolimod)	S1P receptor functional antagonist (Pediatric multiple sclerosis)	Europe Filed (Nov. 2017)	Europe Approved (Nov. 2018)	Licensed to Novartis (Switzerland)
TAU-284 Talion (Bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent (Allergic rhinitis, Urticaria)	None	Thailand Filed (Nov. 2018)	Licensed from Ube Industries (Japan)
MP-513 Tenelia (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	None	Malaysia Filed (Dec. 2018)	In-house
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist (Schizophrenia)	None	Indonesia Filed (Dec. 2018)	Licensed from Gedeon Richter (Hungary)
		Korea Filed (Dec. 2017)	Deleted (Change of license agreement with Gedeon Richter)	
		Taiwan Filed (Dec. 2017)		
MT-6345	Nervous system	None	Phase 1	Co-developed with Ube Industries (Japan)
MT-2765	Cardiovascular system, etc.	Phase 1	Deleted (Transfer of patent and know-how to Shanghai Pharmaceuticals Holding)	Co-researched with Shanghai Pharmaceuticals Holding (China)