

6 State of New Product Development (as of April 30, 2018)

(1) Autoimmune diseases

Development code Product name (Generic name)	Category (Indications)	Region Stage	Origin/licensee
FTY720 Imusera/Gilenya (Fingolimod)	S1P receptor functional antagonist (Pediatric multiple sclerosis)	Europe Filed(Nov.,2017)	Licensed to Novartis (Switzerland)
		US Filed(Nov.,2017)	
MT-5547 (Fasinumab)	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. (Inflammatory diseases, autoimmune diseases, etc.)	Phase 1	In-house
MT-2990	Inflammatory diseases, autoimmune diseases, etc.	Phase 1	In-house

(2) 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
	(Reduce the risk of death in type 2 diabetes with established, or risk for, cardiovascular disease (CANVAS/CANVAS-R))	US Filed(Sep., 2017)	Licensed to Janssen Pharmaceuticals (US)
		Europe Filed(Oct., 2017)	
	(Diabetic nephropathy)	Japan, US, Europe, and others Phase 3 (Global clinical trial)	Discovered in-house Sponsor: Janssen Research & Development (US)
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Indonesia Filed(Apr., 2015)	In-house
		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	

(3) 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)	Switzerland Filed(Dec., 2017)	In-house
		Canada Filed(Apr., 2018)	
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist (Schizophrenia)	Korea Filed(Dec., 2017)	Licensed from Gedeon Richter (Hungary)
		Taiwan Filed(Dec., 2017)	
MT-210	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
ND0801 (Nicotine/Opipramol)	Transdermal (CNS disease cognition disorders)	Israel 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 / New administration route)	Phase 1	In-house

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

(4) 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)	US, Europe, Canada, and others Phase 3	In-house
MT-8972	Plant-based VLP vaccine (Prophylaxis of H5N1 influenza)	Canada Phase 2	In-house
MT-7529	Plant-based VLP vaccine (Prophylaxis of H7N9 influenza)	Phase 1	In-house

(5) Other diseases

Development code Product name (Generic name)	Category (Indications)	Region Stage	Origin/licensee
Valixa (valganciclovir)	Anti-cytomegalovirus chemotherapeutic agent (Prevention of cytomegalovirus disease in pediatric organ transplant patients)	Japan Filed(Feb.,2018)	Licensed from F. Hoffmann- La Roche (Switzerland)
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)
GB-1057 (Recombinant human serum albumin)	Blood and blood forming organs	Phase 1	In-house
MT-0814	Ophthalmologicals	Phase 1	In-house
MT-4129	Cardiovascular system, etc.	Phase 1	In-house
MT-2765	Cardiovascular system, etc.	Phase 1	Co-researched with Shanghai Pharmaceuticals Holding (China)

Changes Since Previous Announcement on Feb 5, 2018

Development code Product name (Generic name)	Category (Indications)	Previous Announcement	As of Apr 30, 2018	Origin / licensee
MT-4580 Orkedia (Evocalcet)	Ca sensing receptor agonist (Secondary hyperparathyroidism in chronic kidney disease patients on maintenance dialysis)	Japan Filed (Apr.,2017)	Japan Approved (Mar.,2018)	Licensed to Kyowa Hakko Kirin(Japan)
Valixa (valganciclovir)	Anti-cytomegalovirus chemotherapeutic agent (Prevention of cytomegalovirus disease in pediatric organ transplant patients)	None	Japan Filed (Feb.,2018)	Licensed from F. Hoffmann-La Roche (Switzerland)
MCI-186 Radicut/Radicava (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis)	None	Canada Filed (Apr.,2018)	In-house
MT-1186 (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis / New administration route)	None	Phase 1	In-house
sTU-199 (Tenatoprazole)	Alimentary tract and metabolism	Europe Phase 1	Deleted (Discontinued)	Licensed to Negma/Sidem (France)