6 State of New Product Development (As of November 1, 2017)

i. Autoimmune diseases

Development code (Generic name)	Category (Indications)	Region	Stage	Origin/licensee
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-7117	Dermatologicals, etc. (Inflammatory diseases, autoimmune diseases, etc.)	Europe	Phase 1	In-house
MT-2990	Inflammatory diseases, autoimmune diseases, etc.	Europe	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
	(Reduce the risk of death in Type 2 diabetes with established, or risk for, cardiovascular disease (CANVAS/CANVAS-R))	US	Filed (Sep., 2017)	Discovered in-house 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	
		US	Phase 1	
MT-3995 (apararenone)	Selective mineralocorticoid receptor antagonist (Diabetic nephropathy)	Europe	Phase 2	In-house
		Japan	Phase 2	
		US	Phase 1	
	(Non-alcoholic steatohepatitis: NASH)	Japan	Phase 2	
MT-6548 (vadadustat)	Hypoxia inducible factor prolyl hydroxylase inhibitor (Renal anemia)	Japan	Phase 2	Licensed from Akebia (US)

iii. Central nervous system diseases

Development code (Generic name)	Category (Indications)	Region	Stage	Origin/licensee
MT-5199 (valbenazine)	Vesicular monoamine transporter type 2 inhibitor (Tardive dyskinesia)	Japan	Phase 2/3	Licensed from Neurocrine Biosciences(US)
MT-210	5-HT2A/ Sigma 2 receptor antagonist (Schizophrenia)	Europe	Phase 2	Licensed to Minerva Neurosciences(US)
Wf-516	Multiple mechanisms on several receptors* (Major depressive disorder)	Europe	Phase 2	Licensed to Minerva Neurosciences(US)
MT-8554	Nervous system, etc. (Painful Diabetic Peripheral Neuropathy)	Europe	Phase 2	In-house
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	US	Phase 1	In-house
ND0701 (Apomorphine)	Continuous SC pump (Parkinson's disease)	Europe	Phase 1	In-house

*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)	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)	Canada	Phase 1	In-house

v. Other diseases

Development code Product name (Generic name)	Category (Indications)	Region	Stage	Origin/licensee
Novastan (argatroban)	Selective antithrombin agent (Acute cerebral infarction)	China	Filed (Feb., 2017)	In-house
MT-4580 (evocalcet)	Ca sensing receptor agonist (Secondary hyperparathyroidism in chronic kidney disease patients on maintenance dialysis)	Japan	Filed (Apr., 2017)	Licensed to Kyowa Hakko Kirin(Japan)
	(Hypercalcemia in Patients with Parathyroid Carcinoma or Primary Hyperparathyroidism)	Japan	Phase 3	
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	US	Phase 1	In-house
MP-157	Cardiovascular system	Europe	Phase 1	In-house
MT-0814	Ophthalmologicals	Japan	Phase 1	In-house
sTU-199 (tenatoprazole)	Alimentary tract and metabolism	Europe	Phase 1	Licensed to Negma/Sidem (France)
MT-4129	Cardiovascular system, etc.	Europe	Phase 1	In-house
MT-2765	Cardiovascular system, etc.	China	Phase 1	Co-researched with Shanghai Pharmaceuticals Holding(China)

Changes Since Previous Announcement on July 31, 2017

Development code Product name (Generic name)	Category (Indications)	Region	As of July 31, 2017	As of Nov 1, 2017	Origin / licensee
TA-7284 Canaglu/ INVOKANA (canagliflozin)	SGLT2 inhibitor (Type 2 diabetes mellitus)	Indonesia	None	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	None	Filed (Sep., 2017)	Discovered in-house Licensed to Janssen Pharmaceuticals (US)
		Europe	None	Filed (Oct., 2017)	
MT-5199 (valbenazine)	Vesicular monoamine transporter type 2 inhibitor (Tardive dyskinesia)	Japan	Phase 1	Phase 2/3	Licensed from Neurocrine Biosciences (US)
MT-2271	Plant-based VLP vaccine (Prophylaxis of seasonal influenza)	US, Europe, Canada, and others	Phase 2	Phase 3	In-house
MT-4580 (evocalcet)	Ca sensing receptor agonist (Hypercalcemia in Patients with Parathyroid Carcinoma or Primary Hyperparathyroidism)	Japan	None	Phase 3	Licensed to Kyowa Hakko Kirin (Japan)
MT-8554	Nervous system, etc. (Painful Diabetic Peripheral Neuropathy)	Europe	Phase 1	Phase 2	In-house
ND0612 (Levodopa/Carbidopa)	Continuous SC pump/patch pump (Parkinson's disease)	US, Europe	None	Phase 2	In-house
ND0801 (Nicotine/Opipramol)	Transdermal (CNS Disease Cognition disorders)	Israel	None	Phase 2	In-house
MT-2765	Cardiovascular system, etc.	China	None	Phase 1	Co-researched with Shanghai Pharmaceuticals Holding (China)
ND0701 (Apomorphine)	Continuous SC pump (Parkinson's disease)	Europe	None	Phase 1	In-house
FTY720 Imusera/Gilenya (fingolimod)	S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)	Japan, US, Europe, and others	Phase 3 (Global clinical trial)	Deleted (Discontinued)	Discovered in-house Co-developed with Novartis Pharma (Japan) in Japan, licensed to Novartis (Switzerland) overseas
TA-7284 Canaglu/ INVOKANA (canagliflozin)	SGLT2 inhibitor (Type 1 Diabetes Mellitus)	US, Canada	Phase 2	Deleted (Discontinued)	Discovered in-house Licensed to Janssen Pharmaceuticals (US)
	(Obesity / co-administration with phentermine)	US	Phase 2		
MP-214 (cariprazine)	Dopamine D3/D2 receptor partial agonist (Schizophrenia)	Japan, Asia	Phase 2/3	Deleted (Change of license agreement with Gedeon Richter)	Licensed from Gedeon Richter (Hungary)
Y-39983	ROCK (rho-kinase) inhibitor (Glaucoma)	Japan	Phase 2	Deleted (Cancellation of license agreement with Senju Pharmaceutical)	Licensed to Senju Pharmaceutical (Japan)

Reference

Major Ethical Drugs

Remicade (Infliximab)	Launch: May 2002	Category	Anti-TNFα monoclonal antibody

Remicade is an anti-TNFα antibody, which targets TNFα, an important inflammatory cytokine. It is very fast-acting and its efficacy is sustained for eight weeks with a single administration. It has indications for the treatment of rheumatoid arthritis, Crohn's disease, Behcet's disease with refractory uveoretinitis, psoriasis, ankylosing spondylitis, and ulcerative colitis.
In addition, Entero-Behcet's disease, neuro-Behcet's disease, and vasculo-Behcet's disease in cases where existing treatment is inadequate were approved in August, 2015. And Kawasaki disease was approved in December 2015. Partial change in dosage and usage (increased dose) for psoriasis was approved in May 2016. And partial change in administration / dosage of a shortened administration interval for Crohn's disease was approved in May 2017.
Origin: Janssen Biotech

Simponi (Golimumab)	Launch: Sep. 2011	Category	Anti-TNFα monoclonal antibody

Simponi is a human anti-TNFα monoclonal antibody for the treatment of rheumatoid arthritis (including prevention of articular structural damage). It shows a long acting efficacy by subcutaneous injection once every four weeks. Additional indication of ulcerative colitis was approved in March 2017 by Janssen Pharmaceutical.
Origin: Janssen Biotech

Talion (Bepotastine)	Launch: Oct. 2000	Category	Agent for treatment of allergic disorders

Talion has rapid onset of anti-histamine(H1) effects and has been demonstrated to be effective for allergic rhinitis, urticaria, and pruritus accompanying dermatitis. It has minimal incidence of sedation. An additional formulation, orally disintegrating tablets was launched in July 2007. Pediatric indications (from seven to fifteen years old) was approved in May 2015.
Origin: Ube Industries

Tenelia (Teneligliptin)	Launch: Sep. 2012	Category	Selective DPP-IV inhibitor

Tenelia, which Mitsubishi Tanabe has created and developed, is the first DPP-4 inhibitor originating in Japan. It inhibits the function of dipeptidyl peptidase-4 (DPP-4), which selectively breaks down glucagon-like peptide-1(GLP-1), a hormone secreted from the gastrointestinal tract in response to food intake. In this way, Tenelia promotes insulin secretion and suppresses glucagon secretion, thereby demonstrating blood glucose lowering action.

Lexapro (Escitalopram)	Launch: Aug. 2011	Category	Selective sertonin reuptake inhibitor (SSRI)

Lexapro, a highly selective serotonin reuptake inhibitor (SSRI), has been globally approved in 98 countries and regions. It shows good efficacy and tolerability in patients with depressive disorder. Moreover, due to simple dosage and administration, it is expected to improve adherence of the treatment. Social anxiety disorder (SAD) was approved in November 2015.
Origin: H. Lundbeck A/S (Denmark), Manufacturer and distributor: Mochida Pharmaceutical Co., Ltd

Ceredist (Taltirelin)	Launch: Sep. 2000	Category	Agent for treatment of spinocerebellar degeneration

Thyrotropin releasing hormone (TRH) was known to be effective against ataxia caused by spinocerebellar degeneration, but it was previously administered only through injection. Ceredist is the world's first oral TRH derivative drug by in-house development. An additional formulation, orally disintegrating tablets, was launched in October 2009.

Maintate (Bisoprolol)	Launch: Nov. 1990	Category	Selective β1 antagonist (Treatment of hypertension, angina pectoris, and arrhythmias, chronic heart failure)

Maintate is a representative β-blocker used in more than 100 countries around the world. It exhibits high selectivity for β1 receptor and excellent phamacokinetics profiles. It has high efficacy and safety, and evidence-based cardioprotective action. In addition to the indication of chronic heart failure which was approved in May 2011, the indication of atrial fibrillation has been newly approved in June 2013 . Maintate is the only β-blocker with both indications of chronic heart failure and atrial fibrillation in Japan.
Origin: Merck Serono (Germany)

Canaglu (Canagliflozin)	Launch: Sep. 2014	Category	SGLT2 Inhibitor

Canaglu which was discovered by Mitsubishi Tanabe Pharma is a treatment for type 2 diabetes mellitus. It inhibits SGLT2 (sodium glucose co-transporter 2) of kidneys, suppresses the reabsorption of glucose, promotes the excretion of excessive glucose into the urine, and as a result, lowers the blood glucose level. In Overseas markets, licensee Janssen Pharmaceuticals (US) received approval in the US, EU, Australia and more than 78 countries, and this drug is sold under the brand name Invokana (As of Mar. 2017).

Kremezin	Launch: Apr. 2011	Category	Agent for treatment of Chronic renal failure

Kremezin is an oral absorptive charcoal consisting of porous spherical activated carbon of high purity. It absorbs and excretes uremic toxins out of the body. Keremezin was introduced to the Japanese market in December 1991 as the first pharmaceuticals drug in the world for proactive treatment of chronic renal failure (progressive). In April 2011, the marketing rights were transferred from Daiichi Sankyo to MTPC.
Origin, Manufacturer and distributor: Kureha

Radicut (Edaravone)	Launch: Jun. 2001	Category	Free radical scavenger (Cerebral neuroprotectant)

Radicut is the world's first brain protecting agent (free radical scavemger) shown to improve neurological symptoms, interference with activities of daily living, and disability (at hospital discharge) in patients at acute stage of cerebral infarction. Specific indications include the treatment of various types of infarction (cerebral lacunar, atherothrombotic and cardiogenic infarction) It is initiated administration within 24 hours after onset, and is not administrated for more than 14 days. An additional formulation, Radicut bag for I.V. Infusion, was launched in May 2010.
It was designated as an orphan drug of amyotrophic lateral sclerosis (ALS) and approved for ALS in June, 2015.

Imusera (Fingolimod)	Launch: Nov. 2011	Category	Treatment for multiple sclerosis (MS)

Imusera is a first-in-class drug that controls inflammation in the brain and spinal cord in MS. It inhibits the receptor function of sphingosine-1-phosphate receptor (S1P) receptor on the lymphocyte, and prevents auto-aggressive lymphocytes from invading the central nervous system. It can be administered orally (once daily), thereby lowering the burden on patients with MS. It was discovered by Mitsubishi Tanabe Pharma and developed jointly by Mitsubishi Tanabe Pharma and Novartis Pharma in Japan. Mitsubishi Tanabe Pharma is marketing this product under the name Imusera, while Novartis Pharma is marketing it under the name Gilenya.

Urso (Ursodeoxycholic Acid)	Launch: July 1962	Category	Agent for improving hepatic, biliary and digestive functions

Ursodeoxycholic acid (UDCA), principal ingredient of Urso, had been extracted from blackbear's gallbladder in the past and has been used in the treatment of various digestive diseases. It is one of the bile acids existing in the human body. Urso has effects of hapatic protection and indications of improvement of liver function in chronic liver disease and hepatitis C, and dissolution of gallstones.

Infulenza vaccine	Launch: Sep. 1972	Category	Prevention of influenza

It is for prevention of seasonal influenza. It was changed from trivalent vaccine to quadrivalent vaccine in 2015.
Origin, Manufacturer and distributor: BIKEN (The Research Foundation for Microbial Diseases of Osaka University)

TETRABIK	Launch: Oct. 2012	Category	Prevention of diphtheria, pertussis, tetanus and polio

TETRABIK is a combined vaccine that prevents acute poliomyelitis (polio), pertussis, diphtheria and tetanus. It is used at 1st term (initial 3 times) and 1st term (additional 1 time), in total 4 times, of the regular vaccination. By using TETRABIK, It is expected to avoid the very rare occurrence of paralytic symptoms similar to those in natural polio due to live-attenuated oral polio vaccine.
Origin, Manufacturer and distributor: BIKEN (The Research Foundation for Microbial Diseases of Osaka University)

Varicella vaccine	Launch: Mar. 1987	Category	Prevention of varicella and shingles in people 50 or elder

It is for prevention of varicella and included in regular vaccination from 2014. An indication for prevention of shingles in people 50 or elder was approved in 2016.
Origin, Manufacturer and distributor: BIKEN (The Research Foundation for Microbial Diseases of Osaka University)

Mearubik	Launch: Dec. 2005	Category	Prevention of measles and rubella

Mearubik is the combination vaccine for measles and rubella, and children are able to receive both measles and rubella shot at a time with Mearubik, which is used at the 1st term and the 2nd term of its regular vaccination. By both reducing the number of injections and relieving physical pain on people to be vaccinated, It is expected to contribute enhancement of immunization rate for measles and rubella in Japan.
Origin, Manufacturer and distributor: BIKEN (The Research Foundation for Microbial Diseases of Osaka University)