6 State of New Product Development (as of May 10, 2017)

i. Autoimmune diseases

Development code Product name (Generic name)	Category (Indications)	Region	Stage	Origin/licensee
Remicade (infliximab)	Anti-human TNFα monoclonal antibody (Crohn's disease:shortened administration interval)	Japan	Filed (Sep., 2016)	Licensed from Janssen Biotech (US)
Imusera/Gilenya (fingolimod)	S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)	Japan, US, Europe, and others	Phase 3 (Global clinical trial)	Discovered in-house Co-developed with Novartis Pharma (Japan) in Japan, licensed to Novartis (Switzerland) overseas
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

ii. Diabetes and kidney diseases

Development code Product name (Generic name)	Category (Indications)	Region	Stage	Origin/licensee
TA-7284 Canaglu/ INVOKANA (canagliflozin)	SGLT2 inhibitor (Diabetic nephropathy)	Japan, US, Europe, and others	Phase 3 (Global clinical trial)	Discovered in-house Sponsor: Janssen Research & Development (US)
	(Type 1 Diabetes Mellitus)	US, Canada	Phase 2	Discovered in-house Licensed to Janssen Pharmaceuticals (US)
	(Obesity / co-administration with phentermine)	US	Phase 2	
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-2412 (teneligliptin, canagliflozin)	Fixed-dose combination of DPP-4 inhibitor and SGLT2 inhibitor (Type 2 diabetes mellitus)	Japan	Filed (Aug., 2016)	In-house
MT-3995	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
MP-214 (cariprazine)	Dopamine D3/D2 receptor partial agonist (Schizophrenia)	Japan, Asia	Phase 2b/3	Licensed from Gedeon Richter(Hungary)
MT-210	5-HT2A/ Sigma 2 receptor antagonist (Schizophrenia)	Europe	Phase 2	Licensed to Minerva Neurosciences(US)
Wf-516	Multiple mechanisms on several receptors* (Depression)	Europe	Phase 2	Licensed to Minerva Neurosciences(US)
MP-124	Nervous system	US	Phase 1	In-house
MT-8554	Nervous system, etc.	Europe	Phase 1	In-house
MT-5199 (valbenazine)	Vesicular monoamine transporter type 2 inhibitor (Tardive dyskinesia)	Japan	Phase 1	Licensed from Neurocrine Biosciences(US)

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

iv. Vaccines

Development code (Generic name)	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)
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

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	Ca sensing receptor agonist (Secondary hyperparathyroidism in chronic kidney disease patients on maintenance dialysis)	Japan	Filed (Apr., 2017)	Licensed to Kyowa Hakko Kirin(Japan)
Y-39983	ROCK (rho-kinase) inhibitor (Glaucoma)	Japan	Phase 2	Licensed to Senju Pharmaceutical (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	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

Changes Since Previous Announcement on February 6, 2017

Development code Product name (Generic name)	Category (Indications)	Region	As of Feb. 6, 2017	As of May.10, 2017	Origin / licensee
Simponi (golimumab)	Human monoclonal antibody specific for human TNFα (Ulcerative colitis)	Japan	None	Approved (Mar., 2017)	Co-developed by MTPC and Janssen Pharmaceutical K. K. (MA holder)
TA-7284 Canaglu/ INVOKANA (canagliflozin)	SGLT2 inhibitor (Type 2 diabetes mellitus)	Taiwan	Filed (Mar., 2015)	Approved (Mar., 2017)	In-house
MCI-186 (edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis)	US	NDA filed (Jun., 2016)	Approved (May., 2017)	In-house
Novastan (argatroban)	Selective antithrombin agent (Acute cerebral infarction)	China	None	Filed (Feb., 2017)	In-house
MT-4580	Ca sensing receptor agonist (Secondary hyperparathyroidism in chronic kidney disease patients on maintenance dialysis)	Japan	Phase 3	Filed (Apr., 2017)	Licensed to Kyowa Hakko Kirin(Japan)

Additional Information for State of New Product Development (As of May 10, 2017)

(1) Autoimmune diseases

Development code Product name (Generic name)	Information
Remicade (infliximab)	Remicade is an anti-human TNFα monoclonal antibody. In Japan, it was launched as a treatment for Crohn's disease in 2002, followed by rheumatoid arthritis, intractable uveoretinitis caused by Behcet's disease, psoriasis, ankylosing spondylitis, ulcerative colitis, and entero-, neuro-, vasculo-Behcet's disease.
FTY720 Imusera / Gilenya (fingolimod)	Imusera is a sphingosine-1-phosphate receptor functional antagonist, which keeps lymphocytes sequestered in the lymph nodes and prevents them from attacking the myelin of the nerve cells in multiple sclerosis. It was launched as a treatment for multiple sclerosis in 2011 in Japan under the brandname of Imusera. It is also marketed under the brand name of Gilenya by Novartis. Imusera had been jointly developed with Novaltis Pharma for the domestic market. Global Phase 3 study for chronic inflammatory demyelinating polyradiculoneuropathy is underway. It has been jointly developed with Novartis Pharma for the domestic market.
MT-1303 (amiselimod)	MT-1303 is a sphingosine-1-phosphate receptor functional antagonist, which keeps lymphocytes sequestered in the lymph nodes and prevents them from contributing to autoimmune reactions. It's a successor of Imusera/Gilenya.

(2) Diabetes and kidney diseases

Development code Product name (Generic name)	Information
TA-7284 Canaglu / INVOKANA (canagliflozin)	As a selective SGLT2 inhibitor, TA-7284 decreases blood glucose levels by inhibiting reabsorption of glucose in the kidney. It was launched in Japan under the brand name of CANAGLU for the treatment of type2 diabetes mellitus in September 2014, approved in Taiwan in March 2017. It was also launched for the treatment of type2 diabetes mellitus under the brand name of INVOKANA by Janssen Pharmaceuticals, Inc. in the US and its affiliate in Europe. The fixed dose combination with metformin (IR) was approved in Europe (April, 2014) and the US (August, 2014). The fixed dose combination with metformin (XR) was approved in the US (September, 2016).
MP-513 (teneligliptin)	MP-513 selectively inhibits DPP-4, thus accelerates the insulin secretion after meal intake without effect on the fasting insulin secretion. It was launched in Japan for the treatment of type2 diabetes mellitus in September 2012, under the brand name of TENELIA.
MT-2412 (teneligliptin, canagliflozin)	MT-2412 is a fixed-dose combination of teneligliptin(DPP-4 inhibitor) and canagliflozin (SGLT2 inhibitor).
MT-3995	MT-3995 is a selective mineralocorticoid receptor antagonist, which shows renoprotective effect on diabetic nephropathy.
MT-6548 (vadadustat)	MT-6548 is a hypoxia inducible factor prolyl hydroxylase inhibitor, which was licensed from Akebia (US).

(3) Central nervous system diseases

Development code (Generic name)	Information
MP-214 (cariprazine)	MP-214 is a dopamine D3/D2 receptor partial agonist, licensed from Gedeon Richter (Hungary). Efficacy on negative symptoms and cognitive functions in addition to positive symptoms for schizophrenia is expected.
MT-210	MT-210 is a 5-HT2A/ Sigma 2 receptor antagonist.
Wf-516	Wf-516 acts through multiple mechanisms on several receptors* associated with the control of mood. *SSRI, 5-HT1A, dopamine transporter, and alpha-1A and B

(4) Vaccines

Development code (Generic name)	Information
MT-2355	MT-2355 is a combined vaccine for prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants, which has been co-developed with The Research Foundation for Microbial Diseases of Osaka University (Japan).
Influenza vaccine	Plant-based VLP influenza vaccine for prophylaxis of H5N1 influenza.
Influenza vaccine	Plant-based VLP influenza vaccine for prophylaxis of seasonal influenza.
Influenza vaccine	Plant-based VLP influenza vaccine for prophylaxis of H7N9 influenza.

(5) Other diseases

Development code Product name (Generic name)	Information
Novastan (argatroban)	Novastan, discovered and developed by Mitsubishi Tanabe Pharma, is a selective antithrombin agent.
MT-4580	MT-4580 is a Ca sensing receptor agonist.
Y-39983	Y-39983 is a ROCK (Rho-kinase) inhibitor, which relaxes vascular smooth muscles.
MCC-847 (masilukast)	MCC-847 is a leukotriene D4 receptor antagonist.
Y-803	Y-803 is a bromodomain inhibitor.

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 addtion, in July 2009 and August 2011, changes in usage/dosage were approved for rheumatoid arthritis, and Crohn's disease, respectively.
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.
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

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.

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

Tenelia, which Mitsubishi Tanabe pharma 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.

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)

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

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

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

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.

Depas (Etizolam)	Launch: Mar. 1984	Category	Antianxiety agent

Depas is the most widely used anxiolytic agent in Japan. Due to its broad pharmacological properties, Depas shows reasonable effectiveness for psychosomatic disease, neurosis, low back pain, neck pain and muscle-contraction headache, depression and sleep disorder.

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 Japan in June, 2015, in Korea in December, 2015 and in US. in May, 2017.

Imusera (Fingolimod hydrochloride)	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. Unlike previous drug treatments for MS, which are limited to injection, 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. Overseas, Novartis, of Switzerland, which licensed the product, has obtained approval in more than 80 countries, including countries in Europe and the US.

TETRABIK (Absorbed Diphtheria-purified Pertussis-tetanus-inactivated polio	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)

JEBIK V (Cell Culture-derived Japanese Encephalitis Vaccine)	Launch: Jan. 2009	Category	Prevention of Japanese encephalitis

JEBIK V is a freeze-dried preparation containing inactivated Japanese encephalitis virus derived from Vero cells which were used in the manufacturing process as a host to increase the virus. It is used at the 1st term and 2nd term of the regular vaccination. It is expected to reduce the occurrence of ADEM by not using mice's brains in the manufacturing process.
Origin, Manufacturer and distributor: BIKEN (The Research Foundation for Microbial Diseases of Osaka University)

Mearubik (Live Attenuated Measles and Rubella Vaccine)	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)

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)

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)