6 State of New Product Development (As of October 30, 2015)

1. New Drugs

Development code (Generic name)	Category (Indications)	Region	Stage	Origin
TA-650 (infliximab)	Anti-human TNFα monoclonal antibody (Crohn's disease, ulcerative colitis, pediatric Crohn's disease, pediatric ulcerative colitis)	Taiwan	Filed (Sep., 2013)	US:Janssen Biotech
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	
MCI-186 (edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	Korea	Filed (Jun., 2015)	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-4666 (encenicline)	α7nACh receptor agonist (Dementia of Alzheimer's type)	Japan	Phase 2	US: FORUM Pharmaceuticals
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

*Orphan drug designated

2. Additional Indications

Product name (Generic name)	Category (Indications)	Region	Stage	Origin	Notes
Remicade (infliximab)	Anti-human TNFα monoclonal antibody (Refractory Kawasaki disease*)	Japan	sNDA filed (May, 2015)	US:Janssen Biotech	
	(Psoriasis: increased dose)		sNDA filed (Jul., 2015)		
	(Pediatric Crohn's disease)		Phase 3		
	(Pediatric ulcerative colitis)		Phase 3		
Tribik (adsorbed diphtheria-purified pertussis-tetanus combined vaccine)	Vaccine (Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)	Japan	sNDA filed (Apr., 2015)	Japan:The Research Foundation for Microbial Diseases of Osaka University	Co-developed with The Research Foundation for Microbial Diseases of Osaka University
Telavic (telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C, [combination with Feron])	Japan	Phase 3	US:Vertex Pharmaceuticals	
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

*Orphan drug designated

3. 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	Phase 3	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)
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
TA-7906	PDE4 inhibitor (Atopic dermatitis)	Japan	Phase 2	Japan: Maruho
MCC-847 (masilukast)	Leukotriene D4 receptor antagonist (Asthma)	Korea	Phase 2	Korea: SAMA Pharma
MT-4580	Ca sensing receptor agonist (Secondary hyperparathyroidism in hemodialysis patients)	Japan	Phase 2	Japan: Kyowa Hakko Kirin
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

4. Changes Since Previous Announcement on July 31, 2015

(1) In-house Development

Development code/ product name (Generic name)	Category (Indications)	Region	As of July 31, 2015	As of October 30, 2015
Remicade (infliximab)	Anti-human TNFα monoclonal antibody (Entero-, neuro-, and vasculo-Behcet's diseases[*1])	Japan	sNDA filed (Oct., 2014)	Approved (Aug., 2015)
MT-4666 (encenicline)	α7nACh receptor agonist (Dementia of Alzheimer's type)	Japan	Phase 3	Phase 2[*2]

*1 Orphan drug designated

*2 Due to the discontinuation of global phase3 clinical trial program in Japan

(2) Licensing-out

Development code	Category (Indications)	Region	As of July 31, 2015	As of October 30, 2015
TA-8995	CETP inhibitor (Dyslipidemia)	Europe	Phase 2	Deleted *

*Due to the transfer of patent and know-how to Amgen/Dezima

5. Additional Information for State of New Product Development (As of October 30, 2015)

(1) New Drugs

Development code (Generic name)	Information
TA-650 (infliximab)	TA-650 is an anti-human TNFα monoclonal antibody. In Japan, it was launched under the brand name of Remicade® in 2002.
TA-7284 (canagliflozin)	As a selective SGLT2 inhibitor, TA-7284 decreases blood glucose levels by inhibiting reabsportion of glucose in the kidney. It was launched in Japan for the treatment of type2 diabetes mellitus in September 2014, under the brand name of CANAGLU®.
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®.
MCI-186 (edaravone)	MCI-186 is a free radical scavenger. In Japan, it was launched under the brand name of Radicut® for the treatment of the acute stage of cerebral infarction in 2001, followed by Inhibition on progression of functional disorder in patients with Amyotrophic Lateral Sclerosis (ALS) in June, 2015.
MT-2412 (teneligliptin, canagliflozin)	MT-2412 is a fixed-dose combination of Teneligliptin(DPP-4 inhibitor) and Canagliflozin(SGLT2 inhibitor).
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-4666 (encenicline)	MT-4666, licensed from FORUM Pharmaceuticals(US), is an α7nACh receptor agonist, which ameliorates cognitive dysfunction by activation of both the cholinergic system and the glutamatergic system.
MT-3995	MT-3995 is a selective mineralocorticoid receptor antagonist, which shows renoprotective effect on diabetic nephropathy.
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.
MT-2301	MT-2301 is a Haemophilus influenza type b (Hib) vaccine, licensed from Nuron Biotech(US).
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.

(2) Additional Indications

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.
Tribik (Adsorbed diphtheria-purified pertussis-tetanus combined vaccine)	Tribik is a diphtheria-purified pertussis-tetanus combined vaccine. It has been jointly developed with the Research Foundation for Microbial Diseases of Osaka University.
Telavic (telaprevir)	Telavic was launched in Japan for the treatment of chronic hepatitis C (genotype1) in 2011, followed by Chronic hepatitis C (genotype2) in September, 2014.
Imusera (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. 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.
CANAGLU (canagliflozin)	As a selective SGLT2 inhibitor, CANAGLU decreases blood glucose levels by inhibiting reabsportion of glucose in the kidney. It was launched in Japan for the treatment of type2 diabetes mellitus in September, 2014. It was 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.

(3) Licensing-out

Development code (Generic name)	Information
TA-7284 (canagliflozin)	As a selective SGLT2 inhibitor, TA-7284 decreases blood glucose levels by inhibiting reabsorption of glucose in the kidney. It was 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).
FTY720 (fingolimod)	Sphingosine-1-phosphate receptor functional antagonist. It was launched as a treatment for multiple sclerosis under the brandname of Imusera by Mitsubishi Tanabe Pharma in Japan. It is also marketed under the brand name of Gilenya by Novartis.
Y-39983	Y-39983 is a ROCK (Rho-kinase) inhibitor, which relaxes vascular smooth muscles.
MT-210	MT-210 is a 5-HT2A/ Sigma 2 receptor antagonist.
TA-7906	TA-7906 is a PDE4 inhibitor.
MCC-847 (masilukast)	MCC-847 is a Leukotriene D4 receptor antagonist.
MT-4580	MT-4580 is a Ca sensing receptor agonist.
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
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.
It was designated as an orphan drug of refractory Kawasaki disease, and filed for Kawasaki disease in May, 2015.
Partial change in dosage and usage (increased dose) for psoriasis was filed in July, 2015.
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 approved in March and 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, developed by Tanabe, is the world's first oral TRH derivative drug. 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)

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), and co-marketed with Janssen Pharmaceutical. It shows a long acting efficacy by subcutaneous injection once every four weeks, and currently is under development for the ulcerative colitis by Janssen Pharmaceutical.
Origin: Janssen Biotech

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 that has ever been launched. 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 filed in November, 2014.
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.

Anplag (Sarpogrelate)	Launch: Oct. 1993	Category	5-HT2 blocker (Anti-platelet agent)

Anplag, an oral anti-platelet, is used to patients with arteriosclerosis obliterans (ASO) to improve ischemic symptoms like as ulcer, pain and coldness of limbs associated with chronic arterial occlusion. Anplag especially improves the bloodstream of collateral circulation and inhibits platelet aggregation, vascular contraction and growth of vascular smooth muscle cell by antagonistic action to serotonin receptor in platelets and vessels.

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.

TETRABIK (Absorbed Diphtheria-purified Pertussis-tetanus-inactivated polio	Launch: Oct. 31. 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)