6 State of New Product Development (As of May 8, 2015)

i. New Drugs

Development code (Generic name)	Category (Indications)	Region	Stage	Origin
TA-650 (Infliximab [recombinant])	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	
MT-4666	α7nACh receptor agonist (Dementia of Alzheimer's type)	Global clinical trial*	Phase 3	US: FORUM Pharmaceuticals
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-3995	Selective mineralocorticoid receptor antagonist (Diabetic nephropathy)	Europe	Phase 2	In-house
		Japan	Phase 2	
		US	Phase 1	
MT-1303	S1P receptor functional antagonist (Multiple sclerosis)	Europe	Phase 2	In-house
	(Psoriasis)	Europe	Phase 2	
	(Inflammatory diseases, autoimmune diseases)	Japan,Europe, US	Phase1	
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)	Recombinant human serum albumin (Stabilizing agent)	US	Phase 1	In-house
MP-124	PARP inhibitor (Acute ischemic stroke)	US	Phase 1	In-house
MP-157	Angiotensin type 2 receptor agonist (Hypertension)	Europe	Phase 1	In-house
MT-0814	CC chemokine receptor 3 antagonist (Age-related macular degeneration)	Japan	Phase 1	In-house

* Co-developed with FORUM Pharmaceuticals.

ii. Additional Indications

Product name (Generic name)	Category (Indications)	Region	Stage	Origin	Notes
Talion (Bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent (Pediatric allergic rhinitis)	Japan	sNDA filed (May, 2014)	Japan: Ube Industries	
	(Pediatric atopic dermatitis)		sNDA filed (May, 2014)		
Radicut (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	Japan	sNDA filed (Oct., 2014)	In-house	
Remicade (Infliximab [recombinant])	Anti-human TNFα monoclonal antibody (Behcet's disease with special lesions*)	Japan	sNDA filed (Oct., 2014)	US:Janssen Biotech	
	(Refractory Kawasaki disease*)		Phase 3		
	(Pediatric Crohn's disease)		Phase 3		
	(Pediatric ulcerative colitis)		Phase 3		
	(Psoriasis: increased dose)		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

iii. 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	
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 Neuroscience
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
TA-8995	CETP inhibitor (Dyslipidemia)	Europe	Phase 2	Netherlands: DEZIMA Pharma
MT-4580	Ca sensing receptor agonist (Secondary hyperparathyroidism in hemodialysis patients)	Japan	Phase 2	Japan: Kyowa Hakko Kirin
sTU-199 (Tenatoprazole)	Proton pump inhibitor (Gastroesophageal reflux disease)	Europe	Phase 1	France: Negma/Sidem
Wf-516	SSRI / 5HT1A receptor antagonists (Depression)	Europe	Phase 1	US:Minerva Neuroscience
Y-803	Bromodomain inhibitor (Hematological cancer)	Europe, Canada	Phase 1	US: Merck* (Development code: OTX015)
	(Solid cancer)	Europe, Canada	Phase 1	

* Merck acquired OncoEthix, the licensee, in December 2014.

iv. Changes Since Previous Announcement on February 2, 2015

In-house Development

Development code/product name (Generic name)	Category (Indications)	Region	As of February 2, 2015	As of May 8, 2015
TA-650 (Infliximab [recombinant])	Anti-human TNFα monoclonal antibody (Crohn's disease, Ulcerative colitis, Pediatric Crohn's disease, Pediatric ulcerative colitis)	Taiwan	None	Filed (Sep., 2013)
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type 2 diabetes mellitus)	Taiwan	None	Filed (Mar., 2015)
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Indonesia	None	Filed (Apr., 2015)
Tribik (Adsorbed diphtheria-purified pertussis-tetanus combined vaccine)	Vaccine (Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)	Japan	Phase 3	sNDA filed (Apr., 2015)
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	Korea	Phase 1	Discontinued
Telavic (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C, [combination with Pegasys])	Japan	Phase 3	Discontinued
BindRen (Colestilan[INN])	Non-absorbed phosphate binder (Pediatric hyperphosphatemia)	Europe	Phase 3	Discontinued
Cholebine (Colestimide[JAN])	Bile acid signal regulation (Type 2 diabetes mellitus)	Japan	Phase 2	Discontinued
	Non-absorbed phosphate binder (Hyperphosphatemia)		Phase 1	

Licensing-out

Development code (Generic name)	Category (Indications)	Region	As of February 2, 2015	As of May 8, 2015
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type2 diabetes mellitus / fixed dose combination with metformin, XR)	Korea	NDA filed*	Approved (Mar., 2015)
FTY720 (Fingolimod)	S1P receptor functional antagonist (Primary progressive multiple sclerosis)	Global clinical trial	Phase 3	Discontinued

* 20mg/1000mg(teneligliptin/metformin), 10mg/750mg and 10mg/500mg were submitted in Oct., Nov., and Dec. 2014, respectively.

5. Additional Information for State of New Product Development (as of May 8, 2015)

(1) New Drugs

Development code (Generic name)	Information
TA-650 (Infliximab[recombinant])	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®.
MT-4666	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. Clinical stage is Phase 3 for dementia of Alzheimer's type. It is a global clinical trial and co-developed with FORUM Pharmaceuticals.
MT-2412	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-3995	MT-3995 is a selective mineralocorticoid receptor antagonist, which shows renoprotective effect on diabetic nephropathy.
MT-1303	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.
GB-1057(Recombinant human serum albumin)	GB-1057 is a recombinant human serum albumin.
MP-124	MP-124 is a PARP inhibitor that has neuroprotective effect.
MP-157	MP-157 is an angiotensin type2 receptor agonist.
MT-0814	MT-0814 is a CC chemokine receptor 3 antagonist.

(2) Additional Indications

Product name (Generic name)	Information
Talion (Bepotastine)	Talion is a selective histamine H1 receptor antagonist. It was launched as an anti-allergic agent for adult in 2000.
Radicut (Edaravone)	Radicut is a free radical scavenger. In 2001, it was launched for improvement neurological symptoms at the acute stage of cerebral infarction, interference with activities of daily living and functional disability.
Remicade (Infliximab[recombinant])	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, and ulcerative colitis.
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.
TA-8995	TA-8995 is a CETP inhibitor, which raises HDL-C levels and lowers LDL-C levels.
MT-4580	MT-4580 is a Ca sensing receptor agonist.
sTU-199 (Tenatoprazole)	sTU-199 is an isomer of TU-199, developed in Japan, and licensed to Negma (France). Pharmacokinetic/pharmacodynamic results from Phase 1 in Europe and the US demonstrated that sTU-199 controlled gastric acid secretion at nighttime in patients receiving this compound once-daily, with the long half-life. It is expected that this compound could reveal rapid improvement for non-erosive reflux disease.
Wf-516	Wf-516 is a SSRI / 5HT1A receptor antagonists.
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.
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.
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)

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

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.

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.

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.

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. Origin: H. Lundbeck A/S (Denmark), Manufacturer and distributor: Mochida Pharmaceutical Co., Ltd			
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.			
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.			
Herbesser (Diltiazem)	Launch: Feb. 1974	Category	Calcium antagonist (Treatment of angina pectoris and hypertension)
Herbesser is a representative calcium antagonist that is used in more than 110 countries around the world. In addition to a blood pressure lowering effect, it has a cardioprotective action in patients with hypertension or angina pectoris by reducing the cardiac load through a heart rate lowering effect and by increasing the oxygen supply through a coronary vasodilating effect.			
Tanatril (Imidapril)	Launch: Dec. 1993	Category	ACE inhibitor (Treatment of hypertension)
Tanatril shows excellent blood pressure control with effective organ protection as well as minimal incidence of dry cough, a common side effect of ACE inhibitors. With the approval of an additional indication in January 2002, it became the first drug in Japan approved for diabetic nephropathy with type I diabetes mellitus.			
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)			