

5 State of New Product Development (as of May 10, 2011)

1. Pipeline in Japan

(1) New Molecular Entities

Development code (Generic name)	Category (Indications)	Stage	Origin	Remarks
CNTO148 (Golimumab)	Anti-TNF α monoclonal antibody (Rheumatoid arthritis)	NDA filed (Jun. 2010)	US:Centocor Ortho Biotech	Co-development -Janssen Pharmaceutical K.K.
FTY720 (Fingolimod hydrochloride)	Sphingosine-1-phosphate receptor modulator (Multiple sclerosis*)	NDA filed (Dec. 2010)	In-house	Co-development -Novartis Pharma K.K.
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	NDA filed (Jan. 2011)	US:Vertex	
MP-513 (Teneligliptin)	DPP4 Inhibitor (Type 2 Diabetes mellitus)	Phase 3	In-house	
BK-4SP	Vaccine (Prophylaxis of pertussis, diphtheria, tetanus, and poliomyelitis)	Phase 3	The Research Foundation for Microbial Diseases of Osaka University	Co-development -The Research Foundation for Microbial Diseases of Osaka University
MP-214 (Cariprazine)	D3/D2 receptor antagonist (Schizophrenia)	Phase 2	Hungary: Gedeon- Richter	
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type 2 Diabetes mellitus)	Phase 2	In-house	
MP-435	C5a receptor antagonist (Rheumatoid arthritis)	Phase 2	In-house	
MT-4666	α 7nAChR agonist (Alzheimer's disease)	Phase 1	US: EnVivo Pharmaceuticals	

(2) Additional Indications

Development code/Product Name (Generic name)	Category (Indications)	Stage	Origin	Remarks
Venoglobulin IH (Polyethylene glycol treated human normal immunoglobulin)	Human immunoglobulin G (IgG2 deficiency)	sNDA filed (Dec. 1997)	In-house	
	(Systemic sclerosis)	Phase 3		
	(Myasthenia gravis*)	sNDA filed (Dec. 2010)		
Modiodal (Modafinil)	Psychoneurotic agent (Obstructive sleep apnea syndrome)	Filed (May 2010)	US: Cephalon	Co-development -Alfresa Pharma
MCI-9038 (Argatroban)	Thrombin inhibitor (Prevention of the blood clotting/coagulation in under dialysis and percutaneous coronary intervention in patients with heparin-induced thrombocytopenia [HIT])	sNDA filed (Aug. 2010)	In-house	
Maintate (Bisoprolol)	Selective β 1 antagonist (Chronic heart failure)	sNDA filed (Nov. 2010)	Germany : Merck KGaA	
AZANIN (Azathioprine)	Immunosuppressant (Systemic Vasculitis, systemic lupus erythematosus, polymyositis, dermatomyositis, scleroderma, mixed connective tissue disease, intractable rheumatic disease)	sNDA filed (Nov. 2010)	UK: GlaxoSmithKline	
Anti-D Human Immunoglobulin	Anti-D Human Immunoglobulin (Suppression of immunization of the D(Rho) factor [post partum, treatment through pregnancy or for parturition, abdominal bruise etc., and pregnancy around 28 weeks])	sNDA filed (Nov. 2010)	In-house	
Remicade (Infliximab[recombinant])	Anti-TNF α monoclonal antibody (Crohn's disease: dose escalation)	sNDA filed (Dec. 2010)	US: Centocor Ortho Biotech	
Radicut (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis*)	Phase 3	In-house	
Cholebine (Colestimide(JAN))	Bile acid signal regulation (Type 2 diabetes mellitus)	Phase 2	In-house	
	Non-absorbed phosphate binder (Hyperphosphatemia)	Phase 1		

*: Orphan drug designated

2. Pipelines Overseas

(1) New Molecular Entities

Development code (Generic name)	Category (Indications)	Region	Stage	Origin	Remarks
LIVALO (Pitavastatin calcium)	HMG-CoA reductase inhibitor (Hypercholesterolemia, Familial hypercholesterolemia)	Taiwan	NDA filed (Apr. 2010)	Japan: Kowa	Filed by Tai Tien Pharmaceuticals
		Indonesia	NDA filed (Jun. 2010)		Filed by Tanabe Indonesia
MCI-196 (Colestilan(INN))	Non-absorbed phosphate binder (Hyperphosphatemia)	US, Europe	Phase 3	In-house	
MP-146	Uremic toxin adsorbent (Chronic kidney disease)	US, Europe	Phase 3	Japan:Kureha	
MT-2832 (Lunacalcipol)	Vitamin D analog (Secondary hyperparathyroidism)	US, Canada	Phase 2	Canada: Cytochroma	
MCI-186 (Edaravone)	Free radical scavenger (Acute ischemic stroke)	Europe	Phase 2	In-house	
MP-513 (Teneligliptin)	DPP4 inhibitor (Type 2 diabetes mellitus)	Europe	Phase 2	In-house	
		US	Phase 1		
GB-1057 (Human serum albumin[recombinant])	Recombinant human serum albumin (Stabilizing agent)	US	Phase 1	In-house	
TA-8995	CETP inhibitor (Dyslipidemia)	Europe	Phase 1	In-house	
MP-124	PARP inhibitor (Acute ischemic stroke)	US, Canada	Phase 1	In-house	
MP-136	PPAR alpha agonist (Dyslipidemia)	Europe	Phase 1	In-house	
MT-3995	Selective mineralocorticoid receptor antagonist (Hypertention)	Europe	Phase 1	In-house	
MP-157	Angiotensin Type2 Receptor agonist (Hypertention)	Europe	Phase 1	In-house	
MT-1303	Sphingosine-1-phosphate receptor modulator (Multiple sclerosis)	Europe	Phase 1	In-house	

3. Licensing-out

Development code (Generic name)	Category (Indications)	Region	Stage	Licensee
TA-1790 (Avanafil)	PDE5 inhibitor (Erectile dysfunction)	Korea	Filed	Korea: JW Pharmaceutical (ex-Choongwae Pharma)
		US	Phase 3	US: Vivus
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type2 Diabetes mellitus)	US, Europe	Phase 3	US: Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
	(Obesity)	US, Europe	Phase 2	
T-0047 (Finategrast)	Cell adhesion inhibitor [α 4 β 7/ α 4 β 1 inhibitor] (Multiple sclerosis)	Europe	Phase 2	UK:GlaxoSmithKline
MKC-242	5-HT1A receptor agonist (Insomnia)	US	Phase 2	US:MediciNova
MKC-231	Neurogenesis enhancer (Depression/anxiety)	US	Phase 2	US:BrainCells
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	France: Cyrenaic
MKC-733	5-HT3 receptor agonist (Gastroesophageal reflux disease)	US	Phase 2	US: Edusa Pharmaceuticals
sTU-199 (Tenatoprazole)	Proton pump inhibitor (Gastroesophageal reflux disease)	Europe	Phase 1	France:Negma (Sidem)
TT-138	β 3 receptor agonist (Pollakiuria, urinary incontinence)	US	Phase 1	US:MediciNova
TA-7906	PDE4 inhibitor (Atopic dermatitis)	Japan	Phase 1	Japan: Maruho

4. Changes Since Previous Announcement on Jan. 28, 2011

(1) Own Development

Development code (Generic name)	Category (Indications)	As of Jan. 28, 2011	As of May 10, 2011
MCI-9038(Argatroban)	Thrombin inhibitor (Heparin-induced thrombocytopenia (HIT))	Filed in France, Spain (Nov. 2010)	Agreed to approval in France, Spain (Feb. 2011)
MP-157	Angiotensin Type2 Receptor agonist (Hypertention)	Not described	Europe Phase 1
MT-1303	Sphingosine-1-phosphate receptor modulator (Multiple sclerosis)	Not described	Europe Phase 1

(2) Licensing-out

Development code (Generic name)	Category (Indications)	As of Jan. 28, 2011	As of May 10, 2011
FTY720 (Fingolimod hydrochloride)	Sphingosine 1-phosphate receptor modulator (Multiple sclerosis)	Filed in Europe (Dec. 2009)	Approved in EU, Canada (Mar. 2011)
TA-1790 (Avanafil)	PDE5 inhibitor (Erectile dysfunction)	Korea Phase 3	Filed in Korea (Jan. 2011)
MKC-733	5-HT3 receptor agonist (Gastroesophageal reflux disease)	Not described	US Phase 2
TA-2005 (Carmoterol)	Long-acting β 2 receptor agonist (Asthma, COPD)	Europe Phase 2	Termination of Licensing Agreement (Jan. 2011)

5. Additional Information for State of New Product Development

(1) New Molecular Entities in Japan

Development code/Product Name (Generic name)	Information
CNTO148 (Golimumab)	CNTO148 is an anti-TNF α monoclonal antibody, licensed from Centocor Ortho Biotech(US), and co-developed with Janssen Pharmaceutical K.K. NDA was filed in June for rheumatoid arthritis with subcutaneous injections.
FTY720 (Fingolimod hydrochloride)	(Orphan drug designated in September, 2007) FTY720 is a sphingosine-1-phosphate receptor modulator and has been developed with Novartis Pharma K.K. NDA was filed in December 2010 for multiple sclerosis.
MP-424 (Telaprevir)	MP-424 is an orally-available product for treatment of chronic liver diseases due to hepatitis C virus infection, licensed from Vertex (US). This compound inhibits protease NS3/4 in hepatitis C virus. NDA was filed in January 2011.
MP-513 (Teneligliptin)	MP-513 is developed for the treatment of type-2 diabetes mellitus. It selectively inhibits dipeptidyl peptidase 4 (DPP4), thus accelerates the insulin secretion after meal intake. Clinical stage in Japan is Phase 3.
BK-4SP	Diphtheria toxoid-Tetanus toxoid-Bordetella pertussis antigen-Inactivated Poliovirus Combined Vaccine. Co-development with the Research Foundation for Microbial Diseases of Osaka University. Clinical stage is Phase 3.
MP-214 (Cariprazine)	MP-214 is a dopamine D3/D2 receptor antagonist, licensed from Gedeon-Richter (Hungary). Clinical stage is Phase 2 for schizophrenia.
TA-7284 (Canagliflozin)	As a selective SGLT2 inhibitor, TA-7284 decreases blood glucose levels by inhibiting reabsorption of glucose in the kidney. Clinical stage is Phase 2 for type2 diabetes mellitus.
MP-435	MP-435 is a C5a (complement factor) receptor antagonist which modulates the immune system. Clinical stage is Phase 2 for oral antirheumatoid drug.
MT-4666	MT-4666 is an $\alpha 7$ nACh receptor agonist, licensed from EnVivo pharmaceuticals Inc. (US). Clinical stage is Phase 1 for Alzheimer's disease.

(2) Additional Indications in Japan

Development code/Product Name (Generic name)	Information
Venoglobulin IH (Polyethylene glycol treated human normal immunoglobulin)	(IgG2 deficiency) sNDA has been filed.
	(Diffuse systemic scleroderma) Clinical research in Japan demonstrated IV-IG was effective in improvement of skin manifestation, a primary endpoint of systemic scleroderma. Efficacy of IV-IG was also reported in overseas studies. Clinical stage is Phase 3. It was designated as an orphan drug at September in 2009.
	(Myasthenia gravis [Orphan drug designated in September 2009]) sNDA was filed in Dec. 2010.
Modiodal (Modafinil)	(Obstructive sleep apnea) sNDA was filed by Alfresa Pharma Corp. in May 2008. As a result of the consultation with PMDA, additional data was required. The additional data was submitted in May 2010.
MCI-9038 (Argatoroban)	(Prevention of the blood coagulation in dialysis and percutaneous coronary intervention in patients with heparin-induced thrombocytopenia [HIT]) sNDA has been filed in August 2010.
Remicade (Infliximab [recombinant])	(Crohn's disease) In order to verify the effectiveness of Remicade when administered in higher doses for patients showing an insufficient response to maintenance therapy. sNDA was filed in Dec. 2010.
Maintate* (Bisoprolol)	(Chronic heart failure) In Europe, the result of the large-scale CIBIS-II trials demonstrated that bisoprolol significantly decreased mortality in patients with chronic heart failure (NYHA III-IV). In Japan, sNDA was filed in November 2010.
AZANIN* (Azathioprine)	(Immunosuppressant) In Japan, sNDA was filed in November 2010, for Systemic Vasculitis, systemic lupus erythematosus, polymyositis/dermatomyositis, scleroderma, mixed connective tissue disease, Intractable rheumatic disease.
Anti-D Human Immunoglobulin*	(Anti-D Human Immunoglobulin) In Japan, sNDA was filed in November 2010, for suppression of immunization of the D(Rho) factor (post partum, treatment through pregnancy or for parturition, abdominal bruise etc., and pregnancy around 28 weeks)
Radicut (Edaravone)	(Amyotrophic lateral sclerosis [Orphan drug designated in June, 2005]) Clinical stage is Phase 3.
Cholebine (Colestimide(JAN))	(Type 2 diabetes mellitus) Clinical stage is Phase 2.
	(Hyperphosphatemia) Clinical stage is Phase 1.

*; Correspondent to the review committee on unapproved drugs and indications with high medical needs

(3) New Molecular Entities Overseas

Development code/Product Name (Generic name)	Information
LIVALO (Pitavastatin calcium)	LIVALO is HMG-CoA reductase inhibitor, licensed from Kowa Co., Ltd. (Japan) in August 2009. NDAs have been filed in Taiwan and Indonesia by the overseas subsidiaries. It is marketed by Kowa Co., Ltd. in Japan under the brand name, LIVALO®.
MCI-196 (Colestilan(INN))	MCI-196 is anion-exchange resin, and has been developed for the treatment of hyperphosphatemia in patients on dialysis in Europe and the US. Clinical stage is Phase 3. It is marketed in Japan for the treatment of hypercholesterolemia, under the brand name of CHOLEBINE®.
MP-146	MP-146 is spherical carbon adsorbent, licensed from KUREHA CORPORATION (Japan) in November 2006. Clinical stage is Phase 3 for Chronic Kidney Disease patients in Europe, North America and South America. It has been marketed by Daiichi Sankyo Co. Ltd. in Japan from 1991 under the brand name, KREMEZIN®. In April 2011, Mitsubishi Tanabe Pharma Corporation has succeeded its marketing from Daiichi Sankyo.
MT-2832 (Lunacalcipol)	MT-2832 was licensed from Cytochroma Inc. (Canada) in July 2008. MT-2832 is a strong activator of the vitamin D signaling pathway and has a resistance characteristics to CYP24, intracellular enzyme responsible for catabolism of Vitamin D hormones. Clinical stage is Phase 2 for secondary hyperparathyroidism in patients with chronic kidney disease in Canada.
MCI-186 (Edaravone)	MCI-186 is the world's first cerebral neuroprotectant (free radical scavenger). Clinical stage in Europe is Phase 2 for the acute ischemic stroke. It is marketed in Japan under the brand name, Radicut®.
MP-513 (Teneligliptin)	MP-513 is developed for the treatment of type-2 diabetes mellitus. It selectively inhibits dipeptidyl peptidase 4 (DPP4), thus accelerates the insulin secretion after meal intake. Clinical stages in the US and Europe are Phase1 and Phase 2, respectively.
GB-1057 (Human serum albumin [recombinant])	GB-1057 is a recombinant human serum albumin. Clinical stage is Phase 1 as a stabilizing agent in the US.
TA-8995	TA-8995 is a CETP inhibitor that has raising the HDL-C and lowering the LDL-C effects. Clinical stage is Phase 1 in Europe.
MP-124	MP-124 is a PARP inhibitor that has neuroprotective effect. Clinical stages in the US and Canada are Phase 1 for acute ischemic stroke.
MP-136	MP-136 is a PPAR alpha agonist. Clinical stage is Phase 1 in Europe for dyslipidemia.
MT-3995	MT-3995 is a selective mineralocorticoid receptor antagonist. Clinical stage is Phase 1 in Europe for hypertension.
MP-157	MP-157 is a Angiotensin Type2 Receptor Agonist. Clinical stage is Phase 1 in Europe for hypertension.
MT-1303	MT-1303 is a sphingosine-1-phosphate receptor modulator. Clinical stage is Phase1 in Europe for multiple sclerosis.

(4) Licensing-out

Development code/Product Name (Generic name)	Information
TA-1790 (Avanafil)	TA-1790 is developed for the treatment of erectile dysfunction by Mitsubishi Tanabe Pharma, which is expected to have a quick onset and fewer side effects. Clinical trial stage is Phase 3 in the US and filed in Korea.
TA-7284 (Canagliflozin)	As a selective SGLT2 inhibitor, TA-7284 decreases blood glucose levels by inhibiting reabsorption of glucose in the kidney. Phase 3 clinical trials in diabetes mellitus in Europe and the US are underway by Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Phase 2 clinical trials in obesity in Europe and the US are completed.
T-0047(Firategrast)	T-0047 inhibits the cell adhesion and cell migration processes of white blood cells in inflammatory region. Phase 2 trial is conducted by GSK in Europe, Canada, Australia, and New Zealand.
MKC-242	MKC-242 is a serotonin 1A receptor agonist, used to treat psychiatric disorders such as anxiety and depression. This compound is expected to reveal rapid onset with low possibility of dependency. Medici Nova Inc.(US) is conducting Phase 2 clinical trials in patients with generalized anxiety disorder or insomnia.
MKC-231	MKC-231 is a neurogenesis enhancer. Phase 2 study in major depression is underway by BrainCells Inc.(US).
Y-39983	Y-39983 is a ROCK (Rho-kinase) inhibitor, which relaxes vascular smooth muscle. Clinical trial stage in Japan is Phase 2 by Senju Pharmaceutical Co. Ltd..
MT-210	MP-210 is a 5-HT2A/ Sigma 2 receptor antagonist. Clinical trial stage is Phase 2 in Europe by Cyrenaic (France).
MKC-733	MKC-733 modulates gastrointestinal motility by agonising serotonin 5-HT3 receptors. Edusa Pharmaceuticals is conducting in the US a phase 2 clinical trial in patients with gastroesophageal reflux disease at night.
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 clinical trials 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 terminal half-life. It is expected that this compound will reveal rapid improvement for non-erosive reflux disease. Sidem Pharma, a subsidiary of Negma, is conducting phase 1 trial for gastroesophageal reflux disease in Europe.
TT-138	TT-138 is a β 3 receptor agonist used to treat pollakiuria and urinary incontinence. Phase 1 study is conducted by Medici Nova Inc. in the US.
TA-7906	TA-7906 is a PDE4 inhibitor. Clinical trial stage is Phase1 for the treatment of atopic dermatitis in Japan by Maruho Co. Ltd.

Reference

Major Ethical Drugs

Remicade (Infliximab)	Launch: May 2002	Category	Anti-TNF α monoclonal antibody (Treatment of rheumatoid arthritis (RA), active Crohn's disease(CD), Behcet 's disease with refractory uveoretinitis, psoriasis and ankylosing spondylitis, moderate to severe ulcerative colitis)
<p>Remicade is an anti-TNFα antibody, which targets TNFα, an important inflammatory cytokine. It is very fast-acting and its efficacy is sustained for two months with a single administration. It was approved in Japan for the treatment of Behcet 's disease with refractory uveoretinitis in January 2007 and for the maintenance treatment of CD in November 2007. Increase of the dosage/shortage of administration interval and the effect on prevention of structural joint damage for the treatment of RA were approved in July 2009. Remicade additionally received approvals for psoriasis in January 2010, for ankylosing spondylitis in April 2010, and for ulcerative colitis in June 2010.</p> <p>Origin: Centocor Ortho Biotech</p>			
Radicut (Edaravone)	Launch: Jun. 2001	Category	Free radical scavenger (Cerebral neuroprotectant)
<p>Radicut is the world's first brain protecting agent (free radical scavenger) 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 approved in January and launched in May 2010.</p>			
Ceredist (Taltirelin)	Launch: Sep. 2000	Category	Agent for treatment of spinocerebellar degeneration
<p>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. In October 2009, An additional formulation, orally disintegrating tablets, was approved in June and launched in October 2009.</p>			
Anplag (Sarpogrelate)	Launch: Oct. 1993	Category	5-HT ₂ blocker (Anti-platelet agent)
<p>Anplag, an oral anti-platelet, is used to patients with arteriosclerosis obliterans (ASO) to improve ischemic symptoms like as lacer, 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. The downsized tablet which is convenient for elderly patients was approved in August 2007.</p>			
Urso (Ursodeoxycholic Acid)	Launch: July 1962	Category	Agent for improving hepatic, biliary and digestive functions
<p>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 human body. Urso has effects of hepatic protection and indications of improvement of liver function in chronic liver disease and hepatitis C, and dissolution of gallstones.</p>			
Talion (Bepotastine)	Launch: Oct. 2000	Category	Agent for treatment of allergic disorders
<p>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.</p> <p>Origin: Ube Industries</p>			
Maintate (Bisoprolol)	Launch: Nov. 1990	Category	Selective β ₁ Antagonist (Treatment of angina pectoris, hypertension, and arrhythmias)
<p>Maintate is a representative β-blocker used in more than 85 countries around the world. It exhibits high selectivity for β₁ receptor and excellent pharmacokinetics profiles. It has high efficacy and safety, and there is evidence for its cardioprotective action.</p> <p>Origin: Merck KGaA</p>			
Depas (Etizolam)	Launch: Mar. 1984	Category	Antianxiety agent
<p>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.</p>			
Tanatril (Imidapril)	Launch: Dec. 1993	Category	ACE Inhibitor (Treatment of hypertension)
<p>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 2002, it became the first drug in Japan approved for diabetic nephropathy with type I diabetes mellitus.</p>			
Herbesser (Diltiazem)	Launch: Feb. 1974	Category	Calcium antagonist (Treatment of angina pectoris and hypertension)
<p>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.</p>			

Venoglobulin IH (Human immunoglobulin)	Launch: Jan. 1992	Category	Plasma derivatives
Venoglobulin IH is intravenous human immunoglobulin derived from donated plasma in Japan. It shows high efficacy on various infectious diseases in combined administration with anti-bacterial agent due to its opsonic, immuno-bacteriolytic and antibody-dependent cytotoxic effects and neutralizing effects on toxins and viruses. In October 2010, the indications for improvement of muscle weakness associated with polymyositis or dermatomyositis were added, and it is expected to be a new treatment option for the diseases that contribute better QOL for patients.			
Liple (Arprostadi)	Launch: Nov. 1988	Category	Chronic arterial occlusion / Circulatory disturbance (PGE1)
Liple, the world's first DDS (Drug Delivery System) agent of intravenous PGE1, improves the peripheral circulatory disturbance and skin ulcer in chronic arterial occlusive disease and diabetes by its direct vasodilating effects. DDS maximizes the therapeutic effects and simultaneously minimizes the adverse effects of PGE1.			
Sermion (Nicergoline)	Launch: Jun. 1988	Category	Cerebral circulation and metabolism ameliorator
Sermion ameliorates blood flow and metabolism in the brain. It is used to treat sequela of cerebral infarction. In 1998, its effectiveness was confirmed in a reevaluation by the Ministry of Health and Welfare in Japan. In "the treatment guidelines for strokes in 2009," Sermion was recommended as a treatment drug for chronic cerebral infarction. Origin: Pfizer			
Neuart (Anti-thrombin III)	Launch: Jun. 1987	Category	Plasma derivatives (Anticoagulant agent)
Neuart is highly purified human anti-thrombin III derived from donated plasma in Japan. It shows strong anticoagulant effects in the treatment of DIC patients by inhibiting various kinds of activated serine protease including thrombin.			
Omeprazon (Omeprazole)	Launch: Apr. 1991	Category	Proton pump inhibitor (Anticancerogenic agent)
Omeprazon is the world's first proton pump inhibitor that suppresses gastric acid secretion. It strongly and sustainably blocks the final step in gastric acid production results in reducing gastric acidity. Omeprazon has excellent efficacy for gastric ulcer, duodenal ulcer and reflux esophagitis. Additional indications for non-erosive reflux disease (NERD) and secondary eradication of Helicobacter pylori were approved in May and August 2007, respectively. Origin: AstraZeneca			
Novastan (Argatroban)	Launch: June 1990	Category	Selective Antithrombin Agents
Novastan is a fully synthesized, selective thrombin inhibitor. In Japan, it was launched in June, 1990 and has been approved for the treatment of limb ulcers, rest pain and a sensation of cold in chronic arterial occlusive disease, the acute treatment of neurological symptoms and activities of daily living for patients with acute-phase cerebral thrombosis, and the prevention of blood clotting in the circuit during hemodialysis in the patients with congenitally decreased antithrombin III levels. In July 2008, it was also approved for the prophylaxis of thrombosis in the patients with type 2 heparin-induced thrombocytopenia (HIT). In overseas market, it was approved by the FDA in 2000 for the prophylaxis or treatment of thrombosis in patient with HIT and has since been approved in nine countries for the same indications.			
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. 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)			
JEBIK V (Cell Culture-derived Japanese Encephalitis)	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. A freeze-dried prepared vaccine is available in routine vaccination. Accordingly, it is expected to increase in number of vaccinated persons. Origin, Manufacturer and distributor: BIKEN (The Research Foundation for Microbial Diseases of Osaka University)			
Kremezin	Launch: Apr. 2011	Category	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. Kremezin was introduced to the Japanese market in December 1991 as the first pharmaceutical 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			