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1993	1993/11/15	(5yaku A) No. 1	2	Mixture of L-arginine and L-arginine hydrochloride granules; L-arginine hydrochloride injection	The granule form treats neurological symptoms due to hyperammonemia, such as vomiting, lethargy, and abnormal electroencephalogram findings, and symptoms due to argenine deficiency, such as growth retardation, which occur in the following diseases: congenital urea cycle enzyme abnormalities (carbomyl phosphate synthetase deficiency, ornithine transcarbamylase deficiency, argininosuccinate synthetase deficiency [citrullinemia], and argininosuccinate lyase deficiency [argininosuccinic aciduria]), and congenital amino acid transfer abnormalities The injection form is for emergency use to lower blood levels of ammonia after it has risen steeply due to wasting syndromes, etc. that have not been controlled with the granule form.	Roussel Morishita Company, Limited	<Argi-U Granule> Inhibition of rising blood levels of ammonia in the following diseases: congenital urea cycle enzyme abnormalities (carbomyl phosphate synthetase deficiency, ornithine transcarbamylase deficiency, argininosuccinate synthetase deficiency [citrullinemia] and argininosuccinate lyase deficiency [argininosuccinic aciduria], or lysinuric protein intolerance, except in patients with strong inhibition of arginine absorption. <Argi-U Injection 20 g> Emergency use to lower blood levels of ammonia in patients with acute exacerbation of hyperammonemia, uncontrollable through oral intake of the granule form in the following diseases: congenital urea cycle enzyme abnormalities (carbomyl phosphate synthetase deficiency, ornithine transcarbamylase deficiency, argininosuccinate synthetase	Argi-U Granule:Ajinomoto Co. Inc. Argi-U Injection 20g:AY PHARMACEUTICALS CO.,LTD	1999/9/22	Argi-U Granule Argi-U Injection 20g	Argi-U® Granule Argi-U® Injection	Argi-U Granule L-Arginine Hydrochloride L-Arginine Argi-U Injection 20g L-Arginine Hydrochloride			Approved
1993	1993/11/15	(5yaku B) No. 2		Alglucerase	Improvement of the following symptoms in patients with Gaucher's disease type I: anemia, thrombocytopenia, and hepatosplenomegaly.	Genzyme Japan K.K.	Improvement of the following symptoms in patients with Gaucher's disease type I: anemia, thrombocytopenia, hepatosplenomegaly and other symptoms in bones.	Genzyme Japan K.K.	1996/7/10	Ceredase injection 50U Ceredase injection 400U	—	Alglucerase	These two formulations are currently not being supplied. Designation number "8yaku No. 81" is being supplied instead.		Approved
1993	1993/11/15	(5yaku A) No. 3	2	Alprostadil Alfadex	Primary hypertension or pulmonary hypertension after open heart surgery; pulmonary hypertension as a complication of collagen diseases	Ono Pharmaceutical Co., Ltd.	—	—	—	—	—	Alprostadil Alfadex	Designation revoked (08/24/2001)	2001/8/24	Revoked
1993	1993/11/15	(5yaku B) No. 4		Albendazole	Echinococcosis	SmithKline Beecham	Echinococcosis	GlaxoSmithKline K.K.	1994/1/19	Eskazole tablet 200mg	Eskazole® Tablets 200mg	Albendazole			Approved
1993	1993/11/15	(5yaku A) No. 5	1	Interferon alpha	HAM (HTLV-I associated myelopathy)	Sumitomo Pharmaceuticals	HTLV-I associated myelopathy (HAM)	Dainippon Sumitomo Pharma Co., Ltd.	2000/1/18	Sumiferon injection vial 3,000,000 IU Sumiferon injection DS 3,000,000 IU	Sumiferon®	Interferon Alfa (NAMALWA)			Approved
1993	1993/11/15	(5yaku B) No. 6		Interferon gamma-1a (recombinant)	Reduction of the frequency and severity of serious infections associated with chronic granulomatous disease	Shionogi & Co., Ltd.	Reduction of the frequency and severity of serious infections associated with chronic granulomatous disease	Shionogi & Co., Ltd.	1998/6/30	Imunomax-γ for injection 50 Imunomax-γ for injection 100	Imunomax®-γ	Interferon Gamma-1a (recombinant)			Approved
1993	1993/11/15	(5yaku B) No. 7		Indomethacin sodium	For use when maintenance therapy including restriction of water intake and diuretics are ineffective for premature infants with patent ductus arteriosus (PDA)	Banyu Pharmaceutical Co., Ltd.	For use when maintenance therapy including restriction of water intake and diuretics are ineffective for premature infants with patent ductus arteriosus (PDA)	Nobelpharma Co., Ltd.	1994/10/5	INDACIN IV 1mg	INDACIN® IV 1mg	Indomethacin sodium			Approved
1993	1993/11/15	(5yaku B) No. 8		Rabbit-derived anti-human thymocyte immunoglobulin	Aplastic anemia	Rhône-Poulenc Japan	Aplastic anemia, moderate or severe cases	Sanofi K.K.	2008/7/16	Thymoglobulin for IV infusion 25mg	Thymoglobulin®	Anti-human Thymocyte Immunoglobulin, Rabbit			Approved
1993	1993/11/15	(5yaku B) No. 9		Rabbit-derived anti-human T-lymphocyte immunoglobulin	Aplastic anemia	Nippon Zoki Pharmaceutical Co., Ltd	Severe to moderate aplastic anemia	Nippon Zoki Pharmaceutical Co., Ltd	1995/9/29	Zetbulin for IV infusion 100mg	Zetbulin® IV drip 100mg	Anti-human T-Lymphocyte Immunoglobulin, Rabbit			Approved
1993	1993/11/15	(5yaku A) No. 10	3	Horse-derived anti-human thymocyte immunoglobulin	Aplastic anemia	Upjohn Pharmaceuticals, Ltd.	—	—	—	—	—	—	Designation revoked (05/28/1998)	1998/5/28	Revoked

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1993	1993/11/15	(5yaku B) No. 11		Horse-derived anti-human thymocyte immunoglobulin	Aplastic anemia	Rhône-Poulenc Japan	Severe to moderate aplastic anemia	Genzyme Japan K.K.	1995/9/29	Lymphoglobulin injection 100mg	—	Anti-human thymocyte immunoglobulin, equine	This formulation is currently not being supplied. Designation number “(5yaku)No. 8” is being supplied instead.		Approved
1993	1993/11/15	(5yaku A) No. 12	2	Botulinum toxin type A	Local dystonia (blepharospasm and torticollis) and facial myokymia	Allergan Japan	Blepharospasm, hemifacial spasm, spasmodic torticollis	GlaxoSmithKline K.K.	1996/10/09 Blepharospasm 2000/01/18 Hemifacial spasm 2001/06/20 Spasmodic torticollis	Botox for injection 50 units Botox for injection 100 units	BOTOX® for injection	Botulinum Toxin Type A			Approved
1993	1993/11/15	(5yaku B) No. 13		Trientine hydrochloride	D-penicillamine intolerance in Wilson’s disease	Tsumura & Co.	Wilson’s disease with D-penicillamine intolerance	Tsumura & Co.	1994/7/1	Metalite 250 capsule	METALITE® 250 CAPSULES	trientine hydrochloride			Approved
1993	1993/11/15	(5yaku A) No. 14	3	Halofantrine hydrochloride	Malaria	SmithKline Beecham Pharmaceutical Co., Ltd.	—	—	—	—	—	—	Designation revoked (1999/05/27)	1999/5/27	Revoked
1993	1993/11/15	(5yaku B) No. 15		Vancomycin hydrochloride	Methicillin-cephem-resistant *Staphylococcus aureus* enteritis	Shionogi & Co., Ltd.	Methicillin-cephem-resistant *Staphylococcus aureus* enteritis	Shionogi & Co., Ltd.	1994/10/5	Vancomycin hydrochloide powder 0.5g	Vancomycin	Vancomycin Hydrochloride			Approved
1993	1993/11/15 2003/11/05 *1	(5yaku A) No. 16, (15yaku) No. 16 *1	5	Freeze-dried concentrated human activated protein C	Improvement of the following diseases caused by congenital protein C deficiency: superficial venous thrombosis, deep venous thrombosis, pulmonary thromboembolism, and purpura fulminans.	Kaketsuken, Teijin Ltd., 1993-11-15, Teijin Pharma Limited, 2003-11-05 *1	The following diseases caused by congenital protein C deficiency: 1. Deep venous thrombosis, acute pulmonary thromboembolism 2. Purpura fulminans	Kaketsuken	2000/09/22 Deep venous thrombosis, acute pulmonary thromboembolism 2006/10/20 Purpura fulminans	Anact C for injection 2,500 units	Anact® C	Freeze-dried Human Activated Protein C Concentrate	Teijin Ltd. only, designation revoked (2003/11/05) *1		Approved
1993	1993/11/15	(5yaku B) No. 17		Freeze-dried BCG vaccine	Superficial bladder cancer and carcinoma in situ of the bladder	Japan BCG Laboratory	Superficial bladder cancer and carcinoma in situ of the bladder	Japan BCG Laboratory	1996/7/10	Immunobladder intravesical 40mg Immunobladder intravesical 80mg	Immunobladder® intravesical 40mg Immunobladder® intravesical 80mg	Freeze-dried BCG for Intravesical Use (Japanese strain)			Approved
1993	1993/11/15	(5yaku A) No. 18	2	Concentrated plasma-derived blood coagulation factor XIII	Suppression of progression of neonatal intracranial hemorrhage	Hoechst Japan, Ltd.	—	—	—	—	—	—	Designation revoked (2000/05/10)	2000/5/10	Revoked
1993	1993/11/15	(5yaku B) No. 19		Corticorelin (human)	Test for function of hypothalamus, pituitary gland and adrenal cortex.	Mitsubishi Kasei Corporation	Test of the ability of the hypothalamus, pituitary gland and adrenal cortex to secrete hormone.	Mitsubishi Tanabe Pharma Corporation	1994/10/5	hCRH Tanabe for IV injection 100μg	hCRH “TANABE” Injection 100μg	Corticorelin (human)			Approved
1993	1993/11/15	(5yaku A) No. 20	2	Zalcitabine	AIDS and HIV infection	Nippon Roche Ltd.	AIDS, symptomatic HIV, and asym	Chugai Pharmaceutical Co., Ltd	1996/4/24	Hibid tablet 0.375mg	—	Zalcitabine	This is currently not supplied.		Approved
1993	1993/11/15	(5yaku B) No. 21		Cyclosporine	Aplastic anemia and pure red-cell aplasia	Sandoz Co., Ltd.	Severe cases of aplastic anemia or pure red-cell aplasia	Novartis Pharma K.K.	1995/9/29	Sandimmun oral solution 10% Sandimmun capsule 25 mg Sandimmun capsule 50 mg	Sandimmun® Oral Solution 10% Sandimmun® Capsules	Cyclosporine			Approved
1993	1993/11/15	(5yaku B) No. 22		Cyclosporine	Frequently recurring or steroid-resistant nephrotic syndrome	Sandoz Co., Ltd	Frequently recurring or steroid-resistant nephrotic syndrome	Novartis Pharma K.K.	1996/1/31	Sandimmun Oral Solution 10% Sandimmun capsule 25 mg Sandimmun capsule 50 mg	Sandimmun® Oral Solution 10% Sandimmun® Capsules	Cyclosporine			Approved
1993	1993/11/15	(5yaku A) No. 23	1	Purified pituitary	Male hypogonadotropic hypogonadism	Serono Japan Co., Ltd.	—	—	—	—	—	—	Designation revoked (2000/09/20)	2000/9/20	Revoked
1993	1993/11/15	(5yaku A) No. 24	3	Sotalol	Life-threatening ventricular tachyarrhythmia (ventricular tachycardia and ventricular fibrillation)	Bristol-Myers Squibb	Life-threatening recurrent arrhythmias (ventricular tachycardia or ventricular fibrillation) where no other antiarrhythmic drugs are effective or usable.	Bristol-Myers	1998/9/30	Sotacor tablet 40 mg Sotacor tablet 80 mg	SOTACOR® TABLETS 40mg SOTACOR® TABLETS 80mg	sotalol hydrochloride			Approved

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1993	1993/11/15	(5yaku B) No. 25		Tacrolimus	Treatment of graft-versus-host disease (GVHD) after bone marrow transplantation	Fujisawa Pharmaceutical Co., Ltd.	Treatment of graft-versus-host disease (GVHD) after bone marrow transplantation	Astellas Pharma Inc.	1994/7/1	Prograf capsule 0.5 mg Prograf capsule 1 mg Prograf capsule 5 mg Prograf granule 0.2 mg Prograf granule 1 mg Prograf injection 2 mg Prograf injection 5 mg	Prograf® Capsules 0.5mg Prograf® Capsules 1mg Prograf® Capsules 5mg Prograf® Granules 0.2mg Prograf® Granules 1mg Prograf® Injection 2mg Prograf® Injection 5mg	Tacrolimus Hydrate			Approved
1993	1993/11/15	(5yaku B) No. 26		Tacrolimus	Inhibition of rejection after renal transplantation	Fujisawa Pharmaceutical Co., Ltd.	Inhibition of rejection after renal transplantation	Astellas Pharma Inc.	1996/4/16	Prograf capsule 0.5 mg Prograf capsule 1 mg Prograf capsule 5 mg Prograf granule 0.2 mg Prograf granule 1 mg Prograf injection 2 mg Prograf injection 5 mg	Prograf® Capsules 0.5mg Prograf® Capsules 1mg Prograf® Capsules 5mg Prograf® Granules 0.2mg Prograf® Granules 1mg Prograf® Injection 2mg Prograf® Injection 5mg	Tacrolimus Hydrate			Approved
1993	1993/11/15	(5yaku A) No. 27	3	Tacrolimus	Refractory uveitis mainly associated with Behcet's disease	Fujisawa Pharmaceutical Co., Ltd.	—	—	—	—	—	Tacrolimus Hydrate	Designation revoked (2000/09/20)	2000/9/20	Revoked
1993	1993/11/15	(5yaku B) No. 28		Dantrolene sodium	Malignant syndrome	Yamanouchi Pharmaceutical Co., Ltd.	Malignant syndrome	Astellas Pharma Inc.	1994/7/1	Dantrium capsule 25 mg Dantrium capsule 50 mg Dantrium 20 mg for IV injection	Dantrium® Capsules 25mg Dantrium® Capsules 50mg Dantrium® 20mg for Intravenous Injection	Dantrolene Sodium Hydrate			Approved
1993	1993/11/15	(5yaku A) No. 29	1	Tretinoin	Acute promyelocytic leukemia	Nippon Roche Ltd.	Acute promyelocytic leukemia	Chugai Pharmaceutical Co., Ltd	1995/1/20	Vesanoid capsule 10 mg	VESANOID® Capsule 10mg	Tretinoin			Approved
1993	1993/11/15	(5yaku A) No. 30	3	Piracetam	Progressive myoclonus epilepsy including dyslipidemia, Unverricht-Lundborg syndrome, Ramsay-Hunt syndrome, Lafora's disease, mitochondrial encephalomyopathy, and neuronal ceroid lipofuscinosis, myoclonus after cerebral anoxia (Lance-Adams syndrome), essential myoclonus, myoclonus caused by Huntington's disease or Alzheimer's disease, drug-induced myoclonus, and other idiopathic myoclonus	Taiho Fine Chemical Taiho Pharmaceutical Co., Ltd. UCB Japan Co. Ltd.	Combination therapy with antiepileptics and other drugs for cortical myoclonus	Taiho Pharmaceutical Co., Ltd. UCB Japan Co. Ltd.	1999/9/22	Myocalm oral solution 33.3%	Myocalm® solution 33.3%	Piracetam			Approved
1993	1993/11/15	(5yaku B) No. 31		Pentostatin	Amelioration of subjective and objective symptoms in the following diseases: adult T-cell leukemia, lymphoma and hairy cell leukemia.	Kaketsuken Yamasa Corporation	Remission of subjective and objective symptoms in the following diseases: adult T-cell leukemia, lymphoma and hairy cell leukemia.	Kaketsuken	1994/4/1	Coforin for IV injection 7.5 mg	Coforin	Pentostatin			Approved
1993	1993/11/15	(5yaku B) No. 32		Mecasermin (recombinant)	Insulin receptor disease (type A and B insulin receptor disease, lipoatrophic diabetes mellitus, leprechaunism and Rabson-Mendenhall syndrome	Fujisawa Pharmaceutical Co., Ltd.	Improvement of hyperglycemia, hyperinsulinemia, acanthosis nigricans or hirsutism in patients with the following diseases: Type A and B insulin receptor disease, lipoatrophic diabetes mellitus, leprechaunism and Rabson-Mendenhall syndrome	Astellas Pharma Inc.	1994/10/5	Somazon 10mg for injection	Somazon® 10mg for Injection	Mecasermin (recombinant)			Approved

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1993	1993/11/15	(5yaku B) No. 33		Mecasermin (recombinant)	Growth hormone resistant dwarfism (isolated growth hormone deficiency Type 1A and Laron dwarfism	Fujisawa Pharmaceutical Co., Ltd.	Improvement of growth disorders in the following diseases: growth hormone resistant isolated growth hormone deficiency Type 1A or Laron dwarfism	Astellas Pharma Inc.	1994/10/5	Somazon 10mg for Injection	Somazon® 10mg for Injection	Mecasermin (recombinant)			Approved
1993	1993/11/15	(5yaku A) No. 34	2	Mesalazine	Ulcerative colitis	Nisshin Flour Milling Inc.	Ulcerative colitis except severe cases	Kyorin Pharmaceutical Co., Ltd.	1996/4/16	Pentasa tablet 250 mg Pentasa tablet 500 mg	PENTASA® Tablets 250mg PENTASA® Tablets 500mg	Mesalazine			Approved
1993	1993/11/15	(5yaku A) No. 35	2 *2	Mesalazine	Crohn's disease	Nisshin Flour Milling Inc.	Crohn's disease	Kyorin Pharmaceutical Co., Ltd.	1996/4/16	Pentasa tablet 250 mg Pentasa tablet 500 mg	PENTASA® Tablets 250mg PENTASA® Tablets 500mg	Mesalazine			Approved
1993	1993/11/15	(5yaku A) No. 36	4	L-1-methyl-4,5-dihydroorotyl-L-histidyl-L-prolineamide	Spinocerebellar ataxia	Tanabe Seiyaku Co., Ltd.	Improvement of ataxia in patients with spinocerebellar ataxia	Mitsubishi Tanabe Pharma Corporation	2000/7/3	Ceredist tablet 5 mg	CEREDIST® Tablets 5mg	taltirelin hydrate			Approved
1993	1993/11/15	(5yaku A) No. 37	2	Melphalan	Multiple myeloma, bone marrow transplantation pretreatment, retinoblastoma	Nihon Wellcome	Pretreatment for hematopoietic stem cell transplantation in the following diseases: leukemia, malignant lymphoma, multiple myeloma, childhood	GlaxoSmithKline K.K.	2001/4/4	Alkeran for IV injection 50mg	Alkeran® for injection	Melphalan			Approved
1993	1993/11/15	(5yaku B) No. 38		*Streptococcus pyogenes* heated with benzylpenicillin potassium and lyophilized	Lymphangioma	Chugai Pharmaceutical Co., Ltd.	Lymphangioma	Chugai Pharmaceutical Co., Ltd.	1995/1/20	Picibanil for injection 0.2 KE Picibanil for injection 0.5 KE Picibanil for injection 1 KE Picibanil for injection 5 KE	PICIBANIL® Injection 0.2KE PICIBANIL® Injection 0.5KE PICIBANIL® Injection 1KE PICIBANIL® Injection 5KE	Lyophilized powder of *Streptococcus pyogenes* (A group, type 3) Su strain cells treated with penicillin			Approved
1993	1993/11/15	(5yaku A) No. 39	4	Riluzole	Amyotrophic lateral sclerosis (ALS)	Rhône-Poulenc Rorer, Inc.	Treatment of amyotropic lateral sclerosis (ALS), inhibition of progression of amyotropic lateral sclerosis (ALS)	Sanofi K.K.	1998/12/25	Rilutek tablet 50 mg	RILUTEK®50mg Tablets	Riluzole			Approved
1993	1993/11/15	(5yaku B) No. 40		Regavirumab	Cytomegalovirus infection in immunocompromised patients with the following conditions: malignant tumors, AIDS, aplastic anemia, organ transplant and newborns	Teijin, Ltd.	—	—	—	—	-	Regavirumab	Designation revoked (1999/05/27)	1999/5/27	Revoked
1994	1994/7/1	(6yaku A) No. 41	3	Ethyl icosapentate	Behcet's disease	Mochida Pharmaceutical Co., Ltd.	—	—	—	—	—	Ethyl icosapentate	Designation revoked (2001/08/24)	2001/8/24	Revoked
1994	1994/7/1	(6yaku A) No. 42	1	Combined formulation of L-isoleucine, L-valine and L-leucine	To maintain muscle strength in amyotrophic lateral sclerosis (ALS) patients with movement disorders in two or fewer body parts	Ajinomoto Co. Inc.	—	—	—	—	—	L-Isoleucine L-valine L-Leucine	Designation revoked (1996/04/01)	1996/4/1	Revoked
1994	1994/7/1	(6yaku A) No. 43	2	Indium 111 (111In)-pentetreotide	Scintigraphic diagnosis of hormone-producing gastrointestinal tract tumors	Marinclott Medical (currently Marinclott Japan)	—	—	—	—	—	'''Indium-pentetreotide			
1994	1994/7/1	(6yaku A) No. 44	3	Interferon-alpha	Extension of survival in patients with subacute sclerosing panencephalitis, used in combination with inosine pranobex	Sumitomo Pharmaceuticals	Inhibition of progression of clincal symptoms in patients with subacute sclerosing panencephalitis, used in combination with inosine pranobex	Dainippon Sumitomo Pharma Co., Ltd.	1999/3/12	Sumiferon injection vial 3,000,000 IU	Sumiferon®	Interferon Alfa (NAMALWA)			Approved
1994	1994/7/1	(6yaku A) No. 45		Interferon alpha	Extension of survival in patients with subacute sclerosing panencephalitis, used in combination with inosine pranobex	Mochida Pharmaceutical Co., Ltd.	—	—	—	—	—	—	Designation revoked (2001/08/24)	2001/8/24	Revoked
1994	1994/7/1	(6yaku A) No. 46	3	Interferon-beta	Extension of survival in patients with subacute sclerosing panencephalitis, used in combination with inosine pranobex	Mochida Pharmaceutical Co., Ltd.	Inhibition of progression of clincal symptoms in patients with subacute sclerosing panencephalitis, used in combination with inosine pranobex	Mochida Pharmaceutical Co., Ltd.	1999/3/12	IFN β MOCHIDA injection 1,000,000 IU IFN β MOCHIDA injection 3,000,000 IU IFN β MOCHIDA injection 5,000,000 IU	—	Interferon Beta	Designation revoked (2009/05/11)	2009/5/11	Approved

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1994	1994/7/1	(6yaku A) No. 47	4	Interferon-beta 1b (recombinant)	Multiple sclerosis	Nihon Schering K.K.	Inhibition of progression or prevention of recurrence of multiple sclerosis	Bayer Holding Ltd.	2000/9/22	Betaferon SC injection 9,600,000 IU	Betaferon®sc inj. 960	Interferon Beta-1b (recombinant)			Approved
1994	1994/7/1	(6yaku A) No. 48	4	Rabbit-derived anti-human thymocyte immunoglobulin	Graft-versus-host disease (GVHD) in bone marrow transplantation	Rhône-Poulenc Japan	Acute graft-versus-host disease (GVHD) after hematopoietic stem cell transplantation	Sanofi K.K.	2008/7/16	Thymoglobulin for infusion 25 mg	Thymoglobulin®	Anti-human Thymocyte Immunoglobulin, Rabbit			Approved
1994	1994/7/1	(6yaku A) No. 49	4	Ursodeoxycholic acid	Primary biliary cirrhosis	Tokyo Tanabe Pharmaceutical Co. Ltd.	Improvement of liver function in patients with primary biliary cirrhosis	Mitsubishi Tanabe Pharma Corporation	1999/6/16	Urso tablet 50 mg Urso tablet 100 mg	URSO® tablets 50mg URSO® tablets 100mg	Ursodeoxycholic Acid			Approved
1994	1994/7/1	(6yaku A) No. 50	4	Epoprostenol sodium	Primary pulmonary hypertension	Nihon Wellcome	Primary pulmonary hypertension	GlaxoSmithKline K.K.	1999/1/25	Flolan for IV injection 0.5 mg Flolan for IV injection 1.5 mg	Flolan® for injection 0.5mg Flolan® for injection 1.5mg	Epoprostenol Sodium			Approved
1994	1994/7/1	(6yaku A) No. 51	3	Mefloquine hydrochloride	Treatment of malaria	SSP Co., Ltd. Dojin Iyaku-Kako Co., Ltd	Malaria	Hisamitsu Pharmaceutical Co., Inc.	2001/4/4	Mephaquin HISAMITSU tablet 275 mg	MEPHAQUIN HISAMITSU TABLETS 275	Mefloquine hydrochloride			Approved
1994	1994/7/1	(6yaku A) No. 52	3	Mefloquine hydrochloride	Treatment of malaria	Nippon Roche Ltd.	—	—	—	—	—	Mefloquine hydrochloride	Designation revoked (2003/01/31)	2003/1/31	Revoked
1994	1994/7/1	(6yaku A) No. 53	1	Octafluoropropane	Support of the repair of idiopathic macular hole	Santen Pharmaceutical Co., Ltd.	—	—	—	—	—	—	Designation revoked (1996/09/25)	1996/9/25	Revoked
1994	1994/7/1	(6yaku A) No. 54	1	Activated human blood coagulation factor VII (recombinant)	Inhibition of hemorrhage in patients who have inhibitors and a deficiency of blood coagulation factor VIII (hemophilia A) or blood coagulation factor IX (hemophilia B)	Novo Nordisk Pharma Ltd.	Inhibition of hemorrhage in patients with congenital or acquired hemophilia who have inhibitors to blood coagulation factor VIII or IX.	Novo Nordisk Pharma Ltd.	2000/3/10	NovoSeven for injection 1.2 mg NovoSeven for injection 4.8 mg NovoSeven HI for IV injection 1 mg NovoSeven HI for IV injection 2 mg NovoSeven HI for IV injection 5 mg	NovoSeven® HI	eptacog alfa (activated)(recombinant)			Approved
1994	1994/7/1	(6yaku A) No. 55	2	Freeze-dried human activated blood coagulation factor VII	Inhibition of hemorrhage in patients who have inhibitors and a deficiency of blood coagulation factor VIII (hemophilia A) or coagulation factor IX (hemophilia B)	Kaketsuken	—	—	—	—	—	—	Designation revoked (2004/04/21)	2004/4/21	Revoked
2000	1994/07/01 2000/12/20 *3	(12yaku) No. 56 *3	3	Dried BCG Vaccine	Superficial bladder cancer and carcinoma in situ of the bladder	Rhône-Poulenc Japan, 1994-7-1, Nippon Kayaku Co., Ltd., 2000-12-20*3	Superficial bladder cancer and carcinoma in situ of the bladder	Sanofi K.K.	2002/10/8	Immucyst intravesical injection 81 mg	IMMUCYST®	Freeze-dried BCG for Intravesical Use (Connaught strain)	Designation revoked (2000/12/20) *3		Approved
1994	1994/7/1	(6yaku A) No. 57	2,2 ※32	Dried polyethylene glycol-treated human immunoglobulin	Chronic inflammatory demyelinating polyradiculoneuropathy	Nihon Pharmaceutical Co., Ltd.	Improvement of muscle weakness in patients with chronic inflammatory demyelinating polyradiculoneuropathy including multifocal motor neuropathy	Nihon Pharmaceutical Co., Ltd.	1999/6/16 ※32	Kenketu glovenin-I for IV injection 500 mg Kenketu glovenin-I for IV injection 2500 mg Kenketu glovenin-I for IV injection 5000 mg	kenketu glovenin®—I for IV injection 500mg kenketu glovenin®—I for IV injection 2500mg kenketu glovenin®—I for IV injection 5000mg	Freeze-dried Polyethylene Glycol-treated Normal Human Immunoglobulin			Approved
1994	1994/7/1	(6yaku A) No. 58	4	Clarithromycin	Disseminated mycobacterial infection in patients with AIDS	Taisho Pharmaceutical Co., Ltd. Dainabot Co., Ltd.	Disseminated mycobacterial infection in patients with AIDS	Taisho Pharmaceutical Co., Ltd. Abbott Japan Co., Ltd.	1998/9/30	Clarith tablet 200 mg Clarith tablet 50 mg for pediatric use Clarith dry syrup 10% for pediatric use Klaricid tablet 200 mg Klaricid tablet 50 mg for pediatric use Klaricid dry syrup 10% for pediatric use	Clarith® tab. 200 Clarith® tab. 50 for pediatric Clarith® dry syrup 10% for pediatric KLARICID TABLETS 200 mg KLARICID SYRUP FOR PEDIATRIC USE KLARICID TABLETS 50 mg FOR PEDIATRIC USE	clarithromycin			Approved
1994	1994/7/1	(6yaku A) No. 59	1	Anti-CD45 monoclonal antibody	Immunosuppression of acute rejection in renal transplantation	Baxter	—	—	—	—	—	—	Designation revoked (1996/04/01)	1996/4/1	Revoked

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1994	1994/7/1	(6yaku A) No. 60	1	Somatropin (recombinant)	Short stature without epiphyseal line closure in chronic renal failure or chondrodystrophy	Novo Nordisk Pharma Ltd.	Short stature without epiphyseal line closure in chondrodystrophy	Novo Nordisk Pharma Ltd.	1997/4/22	Norditropin S injection 10mg Norditropin FlexPro injection 5 mg Norditropin FlexPro injection 10 mg Norditropin FlexPro injection 15 mg	Norditropin® FlexPro® Norditropin® S	somatropin (recombinant)			Approved
1994	1994/7/1	(6yaku A) No. 61	1	Somatropin (recombinant)	Short stature in chronic renal failure without epiphyseal line closure	Sumitomo Pharmaceuticals Co., Ltd.	Short stature in chronic renal failure without epiphyseal line closure	Pfizer Japan Inc.	1997/7/2	Genotropin TC injection 5.3 mg Genotropin TC injection 12 mg Genotropin MiniQuick s.c. injection 0.6 mg Genotropin MiniQuick s.c. injection 1.0 mg Genotropin MiniQuick s.c. injection 1.4 mg Genotropin GoQuick injection 5.3 mg Genotropin GoQuick injection 12 mg	Genotropin® TC Inj. 5.3mg Genotropin® TC Inj. 12mg Genotropin® GoQuick Inj. 5.3mg Genotropin® GoQuick Inj. 12mg Genotropin® MiniQuick s.c. inj. 0.6mg Genotropin® MiniQuick s.c. inj. 1.0mg Genotropin® MiniQuick s.c. inj. 1.4mg	somatropin (recombinant)			Approved
1994	1994/7/1	(6yaku A) No. 62	2	Tiopronin	Cystinuria including lithiasis	Santen Pharmaceutical Co., Ltd.	Cystinuria	Mylan Seiyaku Ltd.	2002/7/5	Thiola tablet 100 mg	Thiola® Tab.100	Tiopronin			Approved
1994	1994/7/1	(6yaku A) No. 63	1	Transforming growth factor - beta 2 (recombinant)	Repair of idiopathic macular hole	Santen Pharmaceutical Co., Ltd.	—	—	—	—	—	—	Designation revoked (1996/09/25)	1996/9/25	Revoked
1994	1994/7/1	(6yaku A) No. 64	2	Phenylalanine reduced milk containing low-phenylalanine peptide powder digested with milk-protein digestive enzymes	Phenylketonuria	Snow Brand Milk Products Co., Ltd.	Phenylketonuria	Snow Brand Milk Products Co., Ltd.	1999/5/25	Snow Brand Peptiderofe	—	—	This is currently not supplied.		Approved
1994	1994/7/1	(6yaku A) No. 65	1	Protirelin	Improvement of ataxia in spinocerebellar ataxia	Takeda Pharmaceutical Co., Ltd.	—	—	—	—	—	Protirelin	Designation revoked (1996/04/01)	1996/4/1	Revoked
1994	1994/7/1	(6yaku A) No. 66	3	Bropirimine	carcinoma in situ of the bladder	Upjohn Pharmaceuticals, Ltd. Yakult Honsha Co., Ltd.	—	—	—	—	—	Bropirimine	Designation revoked (2004/04/21)	2004/4/21	Revoked
1994	1994/07/01 1996/04/01 *4	(6yaku A) No. 67	2 (only Toray) *4	Beraprost sodium	Primary pulmonary hypertension and pulmonary hypertension as a complication of collagen diseases	Toray Industries, Inc., 1994-07-01, Kaken Pharmaceutical Co., Ltd. 1996-04-01 *4	Primary pulmonary hypertension	Toray Industries, Inc. Kaken Pharmaceutical Co., Ltd.	1999/9/22	Dorner tablet 20 μg Procylin tablet 20 μg	DORNER® Tablets 20μg PROCYLIN® Tablets 20	beraprost			Approved
1994	1994/7/1	(6yaku A) No. 68	1	Mycophenolate mofetil	Treatment of refractory rejection after renal transplantation	Nihon Syntex	Treatment of refractory rejection after renal transplantation (when the patient was diagnosed with refractory rejection and existing drugs are ineffective or cannot be administered due to adverse drug reactions, etc.)	Chugai Pharmaceutical Co., Ltd.	1999/9/22	Cellcept capsule 250 mg	CELLCEPT® Capsule 250	Mycophenolate Mofetil			Approved
1994	1994/7/1	(6yaku A) No. 69	4	Fludarabine phosphate	Chronic lymphocytic leukemia with anemia or thrombocytopenia	Nihon Schering K.K.	Chronic lymphocytic leukemia with anemia or with thrombocytopenia	Sanofi K.K.	1999/9/29	Fludara for IV injection 50 mg	Fludara® 50mg	Fludarabine Phosphate			Approved

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1995	1995/4/1	(7yaku A) No. 70	6	N-[(1S,2R)-3-(4-amino-N-isobutylbenzenesulfonamido)-1-benzyl-2-hydroxypropyl]carbamate(3S)-tetrahydro-3-furylester-mesylate	AIDS and symptomatic and asymptomatic HIV infection	Kissei Pharmaceutical Co., Ltd.	HIV-1 infection	Kissei Pharmaceutical Co., Ltd.	1999/9/10	Prozei capsule 150 mg	Prozei	Amprenavir	Designation revoked (2012/12/11)	2012/12/11	Approved
1995	1995/4/1	(7yaku A) No. 71	3	Interferon beta	Senile disciform macular degeneration with foveal neovascularity	Toray Industries, Inc.	—	—	—	—	—	Interferon Beta	Designation revoked (2010/08/11)	2010/8/11	Revoked
1995	1995/4/1	(7yaku A) No. 72	6	Etidronate disodium	Ossification of the posterior longitudinal ligament	Sumitomo Pharmaceuticals Co., Ltd.	—	—	—	—	—	Etidronate Disodium	Designation revoked (2005/08/09)	2005/8/9	Revoked
1995	1995/4/1	(7yaku A) No. 73	4	Cladribine	Hairy cell leukemia	Janssen Kyowa Co., Ltd.	Hairy cell leukemia	Janssen Pharmaceutical K.K.	2002/1/17	Leustatin injection 8 mg	LEUSTATIN® Injection 8mg	cladribine			Approved
1995	1995/4/1	(7yaku A) No. 74	1	Mouse anti-human CD11a monoclonal antibody	Suppression of rejection or graft-versus-host disease (GVHD) in HLA non-compatible bone marrow transplantation in patients with severe combined immunodeficiency disease	Pasteur Mérieux Serums & Vaccines	—	—	—	—	—	—	Designation revoked (2000/05/10)	2000/5/10	Revoked
1995	1995/4/1	(7yaku A) No. 75	3	(R)-N-tertiary-butyl-3-[(2S,3S)-2-hydroxy-3-N-[(R)-2-N-(isoquinolin-5-yloxyacetyl)amino-3-methyl-thio-propanoyl]amino-4-phenylbutanoyl]-1,3-thiazolidine-4-carboxamide	AIDS or symptomatic and asymptomatic HIV infection with 400 or fewer CD4 lymphocytes/ mm3 before treatment	Japan Energy Co., Ltd.	—	—	—	—	—	—	Designation revoked (2002/06/17)	2002/6/17	Revoked
1995	1995/4/1	(7yaku A) No. 76	3	Cyclophosphamide	Pretreatment for bone marrow transplantation for acute leukemia, chronic myelogenous leukemia, myelodysplastic syndrome, malignant lymphoma, multiple myeloma, aplastic anemia, etc.	Shionogi & Co., Ltd.	Pretreatment for hematopoietic stem cell transplantation for the following diseases: acute leukemia, chronic myelogenous leukemia, myelodysplastic syndrome, severe aplastic anemia, malignant lymphoma, hereditary diseases (immunodeficiency, congenital metabolic disorders, congenital hematological disorders: Fanconi anemia, Wiskott-Aldrich syndrome, Hunter's syndrome, etc.)	Shionogi & Co., Ltd.	2003/10/9	Endoxan for injection 100 mg Endoxan for injection 500 mg	Endoxan	Cyclophosphamide Hydrate			Approved
1995	1995/4/1	(7yaku A) No. 77	3	Stavudine	AIDS or HIV infection	Bristol-Myers Squibb	AIDS, HIV infection with ≥500 or fewer CD4 lymphocytes/mm3 before treatment. Monotherapy with this drug should not be used as first-line therapy.	Bristol-Myers Squibb	1997/7/25	Zerit capsule 15 mg Zerit capsule 20 mg	ZERIT® CAPSULES 15 ZERIT® CAPSULES 20	sanilvudine			Approved
1995	1995/4/1	(7yaku A) No. 78	4	Somatropin (recombinant)	Maintenance and increase of fat-free mass in patients with AIDS	Serono Japan Co., Ltd.	Increase and maintenance of fat-free mass in patients with weight loss due to symptomatic HIV infection with ≥200 CD4 lymphocytes/ mm3 or AIDS	Merck Serono Co., Ltd.	1999/3/12	Serostim injection 5 mg	—	—	Designation revoked (2012/06/13)	2012/6/13	Approved
1995	1995/4/1	(7yaku A) No. 79	2	Foscarnet sodium hydrate	Cytomegalovirus retinitis in AIDS patients	Astra Japan, Ltd.	Cytomegalovirus retinitis in AIDS patients	AstraZeneca K.K.	1997/3/28	Foscavir for IV injection 24 mg/mL	Foscavir® Infusion Solution 24mg/Ml	Foscarnet Sodium Hydrate			Approved
1995	1995/4/1	(7yaku A) No. 80	3	Mesna	Prophylaxis for urinary system dysfunction (hemorrhagic cystitis, dysuria, etc.) resulting from cyclophosphamide pre-treatment for bone marrow transplantation	Shionogi & Co., Ltd.	Prophylaxis for urinary system dysfunction (hemorrhagic cystitis, dysuria, etc.) resulting from cyclophosphamide pre-treatment for hematopoietic stem cell transplantation	Shionogi & Co., Ltd.	2003/10/9	Uromitexan for injection 100 mg Uromitexan for injection 400 mg	Uromitexan®	Mesna			Approved

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1996	1996/4/1	(8yaku A) No. 81	1	Imiglucerase	Improvement of various symptoms in patients with Gaucher's disease (anemia, thrombocytopenia, hepatosplenomegaly, bone symptoms, etc.)	Genzyme Japan K.K.	Improvement of various symptoms in patients with Gaucher's disease (anemia, thrombocytopenia, hepatosplenomegaly, bone symptoms, etc.)	Genzyme Japan K.K.	1998/3/6	Cerezyme injection 200 U Cerezyme for IV injection 400 U	CEREZYME® injection	imiglucerase (recombinant)			Approved
1996	1996/4/1	(8yaku A) No. 82	4	Gemcitabine hydrochloride	Pancreatic carcinoma	Eli Lilly Japan K.K	Pancreatic carcinoma	Eli Lilly Japan K.K	2001/4/4	Gemzar for injection 200 mg Gemzar for injection 1 g	Gemzar® Injection	Gemcitabine Hydrochloride			Approved
1996	1996/4/1	(8yaku A) No. 83	3	Sapropterin hydrochloride	Improvement of ataxia in Machado-Joseph disease	Suntory Ltd.	—	—	—	—	—	Sapropterin Hydrochloride	Designation revoked (2003/12/12)	2003/12/12	Revoked
1996	1996/4/1	(8yaku A) No. 84	2	Morphine hydrochloride	Relief of severe pain in various types of cancer when oral administration, intravenous injection or subcutaneous injection of narcotics is not sufficiently effective	Shionogi & Co., Ltd.	—	—	—	—	—	Morphine Hydrochloride Hydrate	Designation revoked (2001/08/24)	2001/8/24	Revoked
1996	1996/4/1	(8yaku A) No. 85		Ofloxacin	Hansen's disease	Daiichi Pharmaceutical Co., Ltd.	Hansen's disease	Daiichi Sankyo Company, Limited	1996/8/9	Tarivid tablet 100 mg	TARIVID® TABLETS 100mg	Ofloxacin			Approved
1996	1996/4/1	(8yaku A) No. 86		Ganciclovir	Maintenance therapy for cytomegalovirus retinitis	Tanabe Seiyaku Co., Ltd.	Maintenance therapy for cytomegalovirus retinitis in AIDS patients stabilized with initial treatment with ganciclovir injection, etc. Prevention of onset of cytomegalovirus retinitis in patients with advanced HIV infection with 100 or fewer CD4 lymphocytes/mm3	Mitsubishi Tanabe Pharma Corporation	1997/7/25	Denosine capsule 250	—	Ganciclovir	Designation revoked (2009/09/11) This is currently not supplied. Designation number (16yaku)No. 169 is supplied instead.	2009/9/11	Approved
1996	1996/4/1	(8yaku A) No. 87	3	Dried sulfonated human immunoglobulin	Severe cases of Guillain-Barre syndrome during acute exacerbations with difficulty in walking	Kaketsuken Teijin, Ltd.	Severe cases of Guillain-Barre syndrome during acute exacerbations with difficulty in walking	Kaketsuken	2000/12/12	Kenketsu Venilon-I for IV injection 500 mg Kenketsu Venilon-I for IV injection 1000 mg Kenketsu Venilon-I for IV injection 2500 mg Kenketsu Venilon-I for IV injection 5000 mg	Kenketsu Venilon®-I Kenketsu Venilon®-I Kenketsu Venilon®-I Kenketsu Venilon®-I	Freeze-dried Sulfonated Normal Human Immunoglobulin			Approved
1996	1996/4/1	(8yaku A) No. 88		Clofazimine	Hansen's disease	Nihon Ciba-Geigy K.K.	Hansen's disease (multibacillary leprosy, lepromatous erythema nodosum)	Novartis Pharma K.K.	1996/11/12	Lampren capsule 50 mg	Lampren® Capsules 50mg	Clofazimine			Approved
1996	1996/4/1	(8yaku A) No. 89		Blood coagulation factor IX (recombinant)	Prevention or treatment of hemorrhage or complications in hemophilia B	Genetics Institute	Reduction of bleeding tendency in patients with hemophilia B (congenital blood coagulation factor IX deficiency)	Pfizer Japan Inc.	2009/10/16	BeneFIX IV injection 500 IU BeneFIX IV injection 1000 IU BeneFIX IV injection 2000 IU	BeneFIX® Intravenous 500 BeneFIX® Intravenous 1000 BeneFIX® Intravenous 2000	Nonacog Alfa (recombinant)			Approved
1996	1996/4/1	(8yaku A) No. 90	4	Anti-TA two hundred twenty-six human monoclonal	Glioma	Japan Pharmaceutical Development Co., Ltd.	—	—	—	—	—	—	Designation revoked (2005/06/20)	2005/6/20	Revoked
1996	1996/4/1	(8yaku A) No. 91	4	Chimeric anti-human TNF alpha monoclonal antibody	Crohn's disease	Tanabe Seiyaku Co., Ltd.	Treatment of Crohn's disease in patients with any of the following conditions, limited to cases where existing treatments are not sufficiently effective: · Moderate to severe active stage · External fistula	Mitsubishi Tanabe Pharma Corporation	2002/01/17 2011/08/17 (new dose) *23	Remicade for IV infusion 100 mg	REMICADE® for IV Infusion 100	infliximab (recombinant)			Approved

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1996	1996/4/1	(8yaku A) No. 92	2	Cytarabine	Relapsed or refractory acute leukemia including blast crisis in chronic myelogenous leukemia	Nippon Shinyaku Co., Ltd.	The following treatments in acute leukemia (acute myelogenous leukemia and acute lymphoblastic leukemia) · Remission induction (salvage treatment) for relapsed or refractory cases · Consolidation therapy Use should be limited to combination therapy with other anti-cancer drugs for acute lymphoblastic leukemia.	Nippon Shinyaku Co., Ltd	2000/1/18	Cylocide N injection 400 mg Cylocide N injection 1 g	Cylocide N Injection 400mg Cylocide N Injection 1g	Cytarabine			Approved
1996	1996/4/1	(8yaku A) No. 93	7, 1 *5	Human thyrotropin alpha (recombinant)	Detection of residual thyroid after thyroidectomy due to thyroid cancer, support of in-vivo diagnostics for detection of metastatic sites of metastatic thyroid cancer and pretreatment for radioactive iodine treatment to enhance uptake of iodine *5	Sato Pharmaceutical Co., Ltd.	Support of diagnostics with radioactive iodine scintigraphy and serum thyroglobulin (Tg) test or with the Tg test alone in patients treated with total or semi-total thyroidectomy due to differentiated thyroid cancer. Support of ablation of residual thyroid by radioactive iodine in patients treated with total or semi-total thyroidectomy due to differentiated non-metastatic thyroid cancer. *5	Genzyme Japan K.K.	2008/10/16 2012/05/25 *5	Thyrogen for IM injection 400 mg	THYROGEN®	Thyrotropin human alfa (recombinant)			Approved
1996	1996/4/1	(8yaku A) No. 94		Fibronectin (human plasma)	Prolonged corneal epithelium impairment when treatment with existing drugs for corneal epithelium impairment for one week or longer shows no effect, and slit-lamp microscope examination clearly shows total loss of the corneal epithelial layer and a curling of the edge of the defect area.	Japan Chemical Research Co., Ltd.	—	—	—	—	—	—	Designation revoked (2004/07/07)	2004/7/7	Revoked
1999	1996/04/01 1999/04/06 *6	(11yaku A) No. 90 *6	1	Lamivudine	Use in combination therapy with zidovudine for AIDS or symptomatic and asymptomatic HIV infection with 500 or fewer CD4 lymphocytes/mm3 before treatment	Nihon Wellcome, 1996-04-01 GlaxoSmithKline K.K., 1999-04-06 *6	Use in combination therapy with zidovudine for HIV infection	ViiV Healthcare K.K.	1997/02/14 1999/06/11 *6	Epivir tablet 150 mg Epivir tablet 300 mg Combivir combination tablet *HC951 Epzicom combination tablet *HC952 Triumeq combination tablet *HC953	EpIVir® Tablets CombIVir® Combination Tablets Epzicom® Combination Tablets Triumeq® Combination Tablets	Lamivudine	Designation revoked (1999/04/06) *6		Approved
1996	1996/4/1	(8yaku A) No. 96	2	Ritonavir	AIDS and HIV Infection	Dainabot Co., Ltd.	Use in combination therapy with nucleoside reverse transcriptase inhibitors in the following diseases · AIDS · symptomatic and asymptomatic HIV infection with 500 or fewer CD4 lymphocytes/mm3 before treatment	AbbVie	1997/11/20	Norvir oral solution 8% Norvir tablet 100 mg Kaletra oral solution *HC961 Kaletra combination tablet *HC961	EpIVir® Tablets CombIVir® Combination Tablets +AS105	Ritonavir			Approved
1996	1996/4/1	(8yaku A) No. 97		Rifampicin	Hansen's disease	Kaken Pharmaceutical Co., Ltd.	Hansen's disease	Kaken Pharmaceutical Co., Ltd.	1996/8/9	Aptecin capsule 150 mg	APTECIN® Capsules 150mg	Rifampicin			Approved
1996	1996/4/1	(8yaku A) No. 98		Rifampicin	Hansen's disease	Kanebo	Hansen's disease	Sandoz	1996/8/9	Rifampicin capsule 150 mg [SANDOZ]	Rifampicin Capsules 150mg [SANDOZ]	Rifampicin			Approved
1996	1996/4/1	(8yaku A) No. 99		Rifampicin	Hansen's disease	Daiichi Pharmaceutical Co., Ltd.	Hansen's disease	Daiichi Sankyo Company, Ltd.	1996/8/9	Rifadin capsule 150 mg	RIFADIN® CAPSULES 150mg	Rifampicin			Approved
1996	1996/4/1	(8yaku A) No. 100		Rifampicin	Hansen's disease	Nihon Ciba-Geigy K.K.	Hansen's disease	Sandoz	1996/8/9	Rimactane capsule 150 mg	—	Rifampicin	This formulation is not currently being supplied.		Approved
1996	1996/4/1	(8yaku A) No. 101		Rifampicin	Hansen's disease	Hishiyama Pharmaceutical	Hansen's disease	Nipro Pharma Corporation	1996/8/9	Rifampicin capsule 150 mg "NP"	—	Rifampicin	This formulation is not currently being supplied.		Approved

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1996	1996/4/1	(8yaku A) No. 102	1	Indinavir sulfate ethanolate	AIDS or symptomatic and asymptomatic HIV infection with 500 of fewer CD4 lymphocytes/mm3 before treatment	Banyu Pharmaceutical Co., Ltd.	・AIDS ・ Symptomatic and asymptomatic HIV infection with 500 or fewer CD4 lymphocytes/mm3 before treatment	MSD K.K.	1997/3/28	Crixivan capsule 200 mg	CRIXIVAN® Capsules 200mg	Indinavir sulfate ethanolate			Approved
1996	1996/9/25	(8yaku A) No. 103	2	Saquinavir mesylate	Use in combination therapy with reverse transcriptase inhibitor for AIDS or symptomatic and asymptomatic HIV Infection	Nippon Roche Ltd.	HIV Infection	Chugai Pharmaceutical Co., Ltd.	1997/9/5	Invirase capsule 200 mg Invirase tablet 500 mg	INVIRASE® Capsule 200mg INVIRASE® Tablet 500mg	Saquinavir Mesylate			Approved
1996	1996/12/20	(8yaku A) No. 104	2	Nevirapine	AIDS or symptomatic and asymptomatic HIV-1 Infection	Nippon Boehringer Ingelheim Co., Ltd.	HIV-1 Infection	Nippon Boehringer Ingelheim Co., Ltd.	1998/11/27	Viramune tablet 200 mg	Viramune® Tablets 200	Nevirapine			Approved
1996	1996/12/20	(8yaku A) No. 105	2	Nelfinavir mesylate	AIDS or symptomatic and asymptomatic HIV Infection	Japan Tobacco, Inc.	HIV Infection	Japan Tobacco, Inc.	1998/03/06 2004/01/19 *7	Viracept tablet 250 mg	Viracept® Tab. 250mg	Nelfinavir mesylate			Approved
1996	1997/3/27	(9yaku A) No. 106	2	8-carbamoyloctyl α-D-galactopyranosyl (1-4) β-D-galactopyranosyl(1-4)-β-D-glucopyranoside siloxypropyldiato	Removal of verotoxin (Shiga-like toxin; SLT) produced by enterohemorrhagic Escherichia coli from the gastrointestinal tract	Takeda Pharmaceutical Co., Ltd.	—	—	—	—	—	—	Designation revoked (2002/03/15)	2002/3/15	Revoked
1996	1997/3/27	(9yaku A) No. 107	1	Clotrimazole	Oral candidiasis in patients with HIV infection	Bayer Holding Ltd.	Mild or moderate oral candidiasis in patients with HIV infection	Bayer Holding Ltd.	1999/6/11	Empecid troche 10 mg	Empecid® Troche	Clotrimazole			Approved
1996	1997/3/27	(9yaku A) No. 108		Fluconazole	Suppression of recurrent cryptococcal meningitis or treatment for oral candidiasis in patients with AIDS	Pfizer Japan Inc.	—	—	—	—	—	Fluconazole			
2001	1997/06/16 2002/01/24 *8	(14yaku) No. 109 *8	3	Verteporfin	Senile disciform macular degeneration with foveal neovascularity	Ciba Vision Corporation, 1997-06-16 Novartis Pharma K.K., 2002-01-24 *8	Age-related macular degeneration with subfoveal choroidal neovascularization	Novartis Pharma K.K.	2003/10/16	Visudyne for IV injection 15 mg	Visudyne®	Verteporfin	Designation revoked (2002/01/24) *8		Approved
1997	1997/6/16	(9yaku A) No. 110	5	1-(2-naphthalene-2-ylethyl)-4-(3-trifluoromethylphenyl)-1,2,3,6-tetrahydropyridine hydrochloride	Amyotrophic lateral sclerosis (ALS)	Sanofi K.K.	—	—	—	—	—	—	Designation revoked (2004/02/06)	2004/2/6	Revoked
1997	1998/3/20	(10yaku A) No. 111	4	Doranidazole	To increase efficacy of intraoperative radiation therapy for pancreatic cancer	Pola Chemical Industries, Inc.	—	—	—	—	—	Doranidazole			
1997	1998/3/20	(10yaku A) No. 112	4	Monteplase (recombinant)	Thrombolysis of acute pulmonary embolism in the pulmonary artery	Eisai Co., Ltd.	Thrombolysis of acute pulmonary embolism in the pulmonary artery with associated unstable hemodynamics	Eisai Co., Ltd.	2005/7/25	Cleactor for IV injection 400,000 IU Cleactor for IV injection 800,000 IU Cleactor for IV injection 1,600,000 IU	Cleactor® for Intravenous Injection 400,000 Cleactor® for Intravenous Injection 800,000 Cleactor® for Intravenous Injection 1,600,000	Monteplase (recombinant)			Approved
1998	1998/9/4	(10yaku A) No. 113	7	5-methyl-1-phenyl-2-(1H)-pyridone	Interstitial pneumonia (except acute cases and acute exacerbation of other cases)	Shionogi & Co., Ltd.	Idiopathic pulmonary fibrosis	Shionogi & Co., Ltd.	2008/10/16	Pirespa tablet 200 mg	Pirespa®	Pirfenidone			Approved
1998	1998/11/27	(10yaku A) No. 114	3	Rituximab	B-cell non-Hodgkin's lymphoma limited to patients with CD20 differentiation antigen on the surface of tumor cells	Zenyaku Kogyo Co., Ltd.	CD20-positive B-cell non-Hodgkin's lymphoma	Zenyaku Kogyo Co., Ltd.	2001/06/20 2003/09/19 *9	Rituxan injection 10 mg/mL(100 mg/10 mL) Rituxan injection 10 mg/mL(500 mg/50 mL)	Rituxan® Injection	Rituximab (recombinant)			Approved
1998	1998/11/27	(10yaku A) No.		Ivermectin	Strongyloidiasis	Banyu Pharmaceutical Co., Ltd.	Intestinal tract strongyloidiasis	MSD K.K.	2002/10/8	Stromectol tablet 3mg	STROMECTOL® Tablets 3mg	Ivermectin			Approved
1998	1998/11/27	(10yaku A) No.	4	Tamibarotene	Acute promyelocytic leukemia	Toko Pharmaceutical Industrial Co., Ltd.	Relapsed or refractory acute promyelocytic leukemia	Toko Pharmaceutical Industrial Co., Ltd.	2005/4/11	Amnolake tablet 2 mg	Amnolake® tablets 2mg	Tamibarotene			Approved

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1998	1999/1/21	(11yaku A) No. 117	5	Human anti-CD33 monoclonal antibody conjugated with calicheamicin	Relapsed or refractory acute myelogenous leukemia	Wyeth Lederle Japan, Ltd.	Relapsed or refractory CD33-positive acute myelogenous leukemia	Pfizer Japan Inc.	2005/7/25	Mylotarg injection 5	MYLOTARG® Injection 5mg	Gemtuzumab ozogamicin (recombinant)			Approved
1998	1999/3/4	(11yaku A) No.	4	Spherical carbon adsorbent	Improvement of fistula in Crohn's disease	Kureha Corporation	—	—	—	—	—	—	Designation revoked (2013/05/13)	2013/5/13	Revoked
1998	1999/03/04 2002/05/28 *10	(14yaku) No. 119 *10	3	Recombinant human growth hormone receptor binding protein	Acromegaly	Sensus Drug Development Corp., 1999-03-04 Pharmacia (currently Pfizer Japan Inc.), 2002-05-28 *10	Improvement of IGF-I (somatomedin C) oversecretion and various symptoms in acromegaly limited to cases where surgical treatment or multiple drug treatment is insufficiently effective or difficult to administer	Pfizer Japan Inc.	2007/1/26	Somavert for SC injection 10 mg Somavert for SC injection 15 mg Somavert for SC injection 20 mg	SOMAVERT® for SC Injection 10mg SOMAVERT® for SC Injection 15mg SOMAVERT® for SC Injection 20mg	Pegvisomant (recombinant)	Designation revoked (2002/05/28) *10		Approved
1998	1999/3/4	(11yaku A) No.		Phenobarbital sodium	Neonatal convulsions	Wyeth Lederle Japan, Ltd.	—	—	—	—	—	Phenobarbital Sodium	Designation revoked (2003/12/12)	2003/12/12	Revoked
1998	1999/3/4	(11yaku A) No.		Relaxin	Scleroderma	Suntory Ltd.	—	—	—	—	—	—	Designation revoked (2002/03/15)	2002/3/15	Revoked
1998	1999/3/4	(11yaku A) No. 122		Tacrolimus hydrate	Generalized myasthenia gravis when post-thymectomy steroid treatment is not sufficiently effective or it cannot be administered due to adverse drug reactions	Fujisawa Pharmaceutical Co., Ltd.	Generalized myasthenia gravis when post-thymectomy steroid treatment is not sufficiently effective or it cannot be administered due to adverse drug reactions *20	Astellas Pharma Inc.	2000/9/22	Prograf capsule 0.5 mg Prograf capsule 1 mg Prograf granule 0.2 mg Prograf granule 1 mg	Prograf® Capsules 0.5mg Prograf® Capsules 1mg Prograf® Granules 0.2mg Prograf® Granules 1mg	Tacrolimus Hydrate			Approved
1998	1999/3/4	(11yaku A) No. 123	5	Interferon beta 1a	Multiple sclerosis	Genzyme Japan K.K.	Prevention of relapse of multiple sclerosis	Biogen Idec Japan Ltd.	2006/7/26	Avonex IM injection syringe 30 μg	AVONEX® IM Injection Syringe	Interferon Beta-1a (recombinant)			Approved
1998	1999/3/4	(11yaku A) No. 124		Vancomycin hydrochloride	Meningitis, septicemia or pneumonia due to high penicillin-resistant *Streptococcus pneumoniae*	Eli Lilly Japan K.K.	Indicated bacterial strains: Vancomycin-sensitive penicillin-resistant Streptococcus pneumonia(PRSP) Indications: Septicemia, pneumonia, purulent meningitis	Shionogi & Co., Ltd.	2004/10/22	Vancomycin Hydrochloride for IV infusion 0.5 g Vancomycin Hydrochloride for IV infusion kit 0.5 g	Vancomycin	Vancomycin Hydrochloride			Approved
1998	1999/3/17	(11yaku A) No.	3	Methionyl human stem cell factor	Aplastic anemia	Amgen	—	—	—	—	—	—	Designation revoked (2003/07/01)	2003/7/1	Revoked
2004	1999/05/27 2004/08/05 2010/07/02 2013/04/04 *11	(11yaku) No. 126 *11	3	Anagrelide hydrochloride, 1999-05-27 Anagrelide hydrochloride, 2010-07-02 *11	Essential thrombocythemia	Robert Pharmaceuticals Co., 1999-05-27 Kirin Brewery Company, Limited (currently Kyowa Hakko Kirin Co., Ltd.), 2004-08-05 Shire Pharmaceuticals Ireland Ltd., 2010-07-02 Shire Japan KK, 2013-04-04 *11	Essential thrombocythemia	Shire Japan KK	2014/9/26	Agrylin Capsules 0.5mg	Agrylin®Capsules 0.5mg	Anagrelide Hydrochloride Hydrate	Designation revoked (2004/08/05) Designation revoked (2010/07/02) Designation revoked (2013/04/04) *11	2004/8/5	Approved
1999	1999/5/27	(11yaku) No. 127	4	α-galactosidase A	Improvement of various symptoms in patients with Fabry's disease	Sumitomo Pharmaceuticals	Fabry's disease	Dainippon Sumitomo Pharma Co., Ltd.	2006/10/20	Replagal for IV infusion 3.5 mg	REPLAGAL®	Agalsidase Alfa (recombinant)			Approved
1999	1999/6/29	(11yaku) No. 128		Efavirenz	AIDS or symptomatic and asymptomatic HIV-1 Infection	Banyu Pharmaceutical Co., Ltd.	HIV-1 infection	MSD K.K.	1999/9/10	Stocrin tablet 200 mg Stocrin tablet 600 mg	STOCRIN® Tablets 200mg STOCRIN® Tablets 600mg	Efavirenz			Approved
1999	1999/7/9	(11yaku) No. 129	5	Abacavir	AIDS or symptomatic and asymptomatic HIV Infection	GlaxoWellcome	HIV infection	ViiV Healthcare K.K.	1999/9/10	Ziagen tablet 300 mg Epzicom combination tablet *HC1291 Triumeq combination tablet *HC1292	Ziagen® Tablets 300mg Epzicom® Combination Tablets Triumeq® Combination Tablets	Abacavir Sulfate			Approved
1999	1999/8/25	(11yaku) No. 130		Basiliximab	Inhibition of acute rejection after renal transplantation	Novartis Pharma K.K.	Inhibition of acute rejection after renal transplantation	Novartis Pharma K.K.	2002/1/17	Simulect IV injection 20 mg Simulect IV injection 10 mg for pediatric use	Simulect® IV injection 20mg Simulect® IV injection 10mg for pediatric	Basiliximab (recombinant)			Approved

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1999	1999/8/25	(11yaku) No. 131	1	Cyclosporine eye drop	Vernal conjunctivitis when anti-allergic drugs are not sufficiently effective	Santen Pharmaceutical Co., Ltd.	Vernal conjunctivitis when anti-allergic drugs are not sufficiently effective	Santen Pharmaceutical Co., Ltd.	2005/10/11	Papilock Mini ophthalmic solution 0.1%	PAPILOCK® Mini ophthalmic solution 0.1%	Cyclosporine			Approved
1999	1999/8/25	(11yaku) No. 132		Trastuzumab	Metastatic breast cancer with overexpression of HER2	Nippon Roche Ltd.	Metastatic breast cancer with overexpression of HER2	Chugai Pharmaceutical Co., Ltd.	2001/4/4	Herceptin for injection 60 mg Herceptin for injection 150 mg	HERCEPTIN® Intravenous Infusion 60 HERCEPTIN® Intravenous Infusion 150	Trastuzumab (recombinant)			Approved
1999	1999/8/25	(11yaku) No. 133	4	α-L-iduronidase	Improvement of various symptoms in patients with mucopolysaccharidosis I	Genzyme Japan K.K.	Mucopolysaccharidosis I	Genzyme Japan K.K.	2006/10/20	Aldurazyme for IV infusion 2.9 mg	ALDURAZYME®	Laronidase (recombinant)			Approved
1999	1999/8/25	(11yaku) No. 134	2	α-galactosidase A	Improvement of various symptoms in patients with Fabry's disease	Genzyme Japan K.K.	Fabry's disease	Genzyme Japan K.K.	2004/1/29	Fabrazyme for IV infusion 5 mg Fabrazyme for IV infusion 35 mg	FABRAZYME®	Agalsidase Beta (recombinant)			Approved
1999	1999/11/24	(11yaku) No. 135	1	Saquinavir	HIV infection	Nippon Roche Ltd.	HIV infection	Chugai Pharmaceutical Co., Ltd.	2000/4/6	Fortovase capsule	—	—	This formulation is no longer being supplied. Designation number "8yaku No. 103" is being supplied instead.		Approved
1999	1999/12/9	(11yaku) No. 136		Delavirdine mesylate	HIV-1 infection	Warner-Lambert	HIV-1 infection	ViiV Healthcare K.K.	2000/2/25	Rescriptor tablet 200 mg	—	Delavirdine Mesylate	Designation revoked (2012/09/13)		Approved
2003	2000/01/06 2003/07/01 *12	(15yaku) No. 137 *12	5	levocarnitine	Erythropoietin-resistant renal anemia in hemodialysis patients	Shimizu Pharmaceutical Co. Ltd., 2000-01-06 Ajinomoto Co. Inc., 2003-07-01 *12	—	—	—	—	—	—	Designation revoked (2003/07/01) Designation revoked (2006/02/03) *12	2003/7/1	Revoked
2002	2000/01/06 2002/12/02 *13	(14yaku) No. 138 *13		Polyethylene glycol-treated human immunoglobulin	Steroid treatment-resistant polymyositis or dermatomyositis (limited to the cases with clear muscle weakness interfering with daily activities)	Yoshitomi Pharmaceutical Co. Ltd., 2000-01-06 Mitsubishi Pharma Corporation, 2002-12-02 *13	Improvement of muscle weakness in polymyositis and dermatomyositis (limited to cases in which steroids are inadequate)	Japan Blood Products Organization	2010/10/27	Venoglobulin IH 5% IV injection 0.5 g/10 mL Venoglobulin IH 5% IV injection 1 g/20 mL Venoglobulin IH 5% IV injection 2.5 g/50 mL Venoglobulin IH 5% IV injection 5 g/100 mL	Venoglobulin® IH5%IV0.5g/10mL Venoglobulin® IH5%IV1g/20mL Venoglobulin® IH5%IV2.5g/50mL Venoglobulin® IH5%IV5g/100mL	Polyethylene Glycol-treated Normal Human Immunoglobulin	Designation revoked (2002/12/02) *13		Approved
1999	2000/1/6	(11yaku) No. 139	6	Modafinil	Narcolepsy	Azwell Inc.	Excessive daytime sleepiness associated with narcolepsy	Alfresa Pharma Corporation	2007/1/26	Modiodal tablet 100 mg	MODIODAL® Tablets 100mg	Modafinil			Approved
2000	2000/4/3	(11yaku) No. 140		Ganciclovir preparation for intraocular implant	Cytomegalovirus retinitis in AIDS	Bausch & Lomb Japan	—	—	—	—	—	—			
2000	2000/6/16	(12yaku) No. 141		Somatropin (recombinant)	Improvement of body composition abnormalities in Prader-Willi syndrome	Pharmacia & Upjohn	Short stature in Prader-Willi syndrome without the epiphyseal closure	Pfizer Japan Inc.	2002/1/17	Genotropin TC injection 5.3 mg Genotropin TC injection 12 mg Genotropin MiniQuick SC injection 0.6 mg Genotropin MiniQuick SC. injection 1.0 mg Genotropin MiniQuick SC injection 1.4 mg Genotropin GoQuick injection 5.3 mg Genotropin GoQuick injection 12 mg	Genotropin® TC Inj. 5.3mg Genotropin® TC Inj. 12mg Genotropin® GoQuick Inj. 5.3mg Genotropin® GoQuick Inj. 12mg Genotropin® MiniQuick s.c. inj. 0.6mg Genotropin® MiniQuick s.c. inj. 1.0mg Genotropin® MiniQuick s.c. inj. 1.4mg	Somatropin (recombinant)			Approved

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2000	2000/9/20	(12yaku) No. 142	5	Follitropin alfa (recombinant)	Male hypogonadotropic hypogonadism	Serono Japan Co., Ltd.	Spermatogenesis induction in male patients with hypogonadotropic hypogonadism	Merck Serono Co., Ltd.	2006/1/23	Gonalef SC injection 75 IU Gonalef SC injection 150 IU Gonalef pen SC injection 300 IU Gonalef pen SC injection 450 IU Gonalef pen SC injection 900 IU	Gonalef® 75 Gonalef® 150 Gonalef® Pen 300 Gonalef® Pen 450 Gonalef® Pen 900	Follitropin alfa (recombinant)			Approved
2000	2000/9/20	(12yaku) No. 143		Lopinavir	HIV infection	Dainabot Co., Ltd	HIV infection	AbbVie	2000/12/12	Kaletra oral solution *HC1431 Kaletra combination tablet *HC1431	Kaletra®	Lopinavir			Approved
2000	2000/12/20	(12yaku) No. 144		4-(4-methyl-piperazine-1-ylmethyl)-N-[4-methyl-3-[(4-pyridine-3-yl)-pyrimidine-2-ylamino]phenyl] benzamide-methanesulfonate	Philadelphia chromosome-positive leukemia	Novartis Pharma K.K.	Chronic myelogenous leukemia, Philadelphia chromosome-positive acute lymphoblastic leukemia	Novartis Pharma K.K.	2001/11/21, Chronic myelogenous leukemia 2007/01/31, Philadelphia chromosome-positive acute lymphoblastic leukemia	Glivec tablet 100 mg	Glivec® Tablets 100mg	Imatinib mesylate			Approved
2000	2000/12/20	(12yaku) No. 145		Humanized anti-interleukin-6 receptor monoclonal antibody (recombinant)	Castleman's disease	Chugai Pharmaceutical Co., Ltd.	Improvement of various symptoms and test results (high C-reactive protein, high fibrinogen, high erythrocyte sedimentation rate, low hemoglobin, low albumin, general malaise) in Castleman's disease. Use should be limited to patients for whom lymphadenectomy is not indicated.	Chugai Pharmaceutical Co., Ltd.	2005/4/11	Actemra for IV infusion 80 mg Actemra for IV infusion 200 mg Actemra for IV infusion 400 mg	ACTEMRA® 80 mg for Intravenous Infusion ACTEMRA® 200 mg for Intravenous Infusion ACTEMRA® 400 mg for Intravenous Infusion	Tocilizumab (recombinant)			Approved
2000	2000/12/20	(12yaku) No. 146		Imidapril hydrochloride	Insulin-dependent diabetic nephropathy	Tanabe Seiyaku Co., Ltd.	Diabetic nephropathy associated with type 1 diabetes mellitus	Mitsubishi Tanabe Pharma Corporation	2002/1/17	Tanatril tablet 2.5 mg Tanatril tablet 5 mg	TANATRIL® Tablets 2.5 TANATRIL® Tablets 5	Imidapril Hydrochloride			Approved
2000	2000/12/20	(12yaku) No. 147		Azithromycin hydrate	Disseminated mycobacterial infection associated with AIDS	Pfizer Japan Inc.	Prophylaxis and treatment of disseminated *Mycobacterium avium* complex (MAC) associated with AIDS	Pfizer Japan Inc.	2001/12/13	Zithromac tablet 600 mg	ZITHROMAC® Tablets 600mg	Azithromycin Hydrate			Approved
2000	2000/11/27	(12yaku) No. 148		Didanosine	HIV infection	Bristol	HIV infection	Bristol-Myers	2001/3/7	Videx EC capsule 125 mg Videx EC capsule 200 mg	VIDEX EC CAPSULES／Enteric-Coated Beadlets VIDEX EC CAPSULES／Enteric-Coated Beadlets	Didanosine			Approved
2001	2001/4/23	(13yaku) No. 149		Dried sulfonated human immunoglobulin	Reduction of frequency of exacerbations in multiple sclerosis (MS), suppression of MS progression	Kaketsuken	—	—	—	—	—	Freeze-dried Sulfonated Normal Human Immunoglobulin	Designation revoked (2012/03/19)	2012/3/19	Revoked
2003	2001/04/23 2003/11/05 *14	(15yaku) No. 150 *14	5	Dried sulfonated human immunoglobulin	Reduction of frequency of exacerbation, attack and relapse of multiple sclerosis (MS), prevention of progression to serious MS	Teijin Ltd., 2001-04-23, Teijin Pharma Limited, 2003-11-05 *14	—	—	—	—	—	Freeze-dried Sulfonated Normal Human Immunoglobulin	Designation revoked (2003/11/05) Designation revoked (2012/03/19) *14	2012/3/19	Revoked

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2001	2001/4/23	(13yaku) No. 151	5	Baclofen (intrathecal continuous infusion)	Severe spastic paralysis caused by cerebral (infantile) palsy, spinal vascular disorder, cervical spondylosis, posterior longitudinal ligament ossification, multiple sclerosis, spinocerebellar degeneration (hereditary spastic paraplegia) or post-traumatic complications of spinal injury or head trauma	Daiichi Pharmaceutical Co., Ltd.	Severe spastic paralysis caused by cerebrospinal disease. Use should be limited to cases in which existing treatment is not sufficiently effective.	Daiichi Sankyo Company, Limited	2005/04/11 2007/01/26 (approval of the expanded age indication)	Gabalon intrathecal injection 0.005% 1 mL Gabalon intrathecal injection 0.05% 20 mL Gabalon intrathecal injection 0.2% 5 mL	GABALON INTRATHECAL INJECTION 0.005% GABALON® INTRATHECAL INJECTION 0.05% GABALON® INTRATHECAL INJECTIONO.2%	Baclofen			Approved
2001	2001/4/23	(13yaku) No. 152	7	Vancomycin ophthalmic ointment	Ocular infections such as blepharitis, conjunctivitis or keratitis caused by methicillin-cephem-resistant *Staphylococcus aureus* or *Staphylococcus epidermidis*	Toa Pharmaceuticals Co., Ltd.	Indicated bacterial strains: Vancomycin-sensitive, methicillin-resistant Staphylococcus aureus (MRSA) or Staphylococcus epidermidis (MRSE) Indications: Conjunctivitis, blepharitis, meibomianitis, and dacryocystitis in which existing treatments are not sufficiently effective	Toa Pharmaceuticals Co., Ltd.	2009/10/16	Vancomycin ophthalmic ointment 1%	Vancomycin Ophthalmic Ointment 1%	Vancomycin Hydrochloride			Approved
2003	2001/04/23 2003/11/05 *15	(15yaku) No. 153 *15	7	Anti-Shiga-like toxin II humanized monoclonal antibody	Inhibition of hemolytic-uremic syndrome, encephalopathy or hemolytic anemia due to *Escherichia coli* infection with Shiga-like toxin II production	Teijin Ltd., 2001-04-23, Teijin Pharma Limited, 2003-11-05 *15	—	—	—	—	—	—	Designation revoked (2003/11/05) Designation revoked (2010/05/13) *15	2003/11/5	Revoked
2001	2001/8/1	(13yaku) No. 154	2	Tiracoxib	Familial adenomatous polyposis	Japan Tobacco, Inc.	—	—	—	—	—	—	Designation revoked (2004/03/22)	2004/3/22	Revoked
2001	2001/8/24	(13yaku) No. 155	3	OPC-31260	Improvement of hyponatremia due to inappropriate secretion of vasopressin	Otsuka Pharmaceutical Co., Ltd.	Improvement of hyponatremia in the syndrome of inappropriate secretion of antidiuretic hormone (SIADH) due to an ectopic antidiuretic hormone-producing tumor. Use should be limited to cases in which existing treatments are not sufficiently effective.	Otsuka Pharmaceutical Co., Ltd.	2006/7/26	Physuline tablet 30 mg	Physuline® tablets 30mg	Mozavaptan Hydrochloride			Approved
2001	2002/3/15	(14yaku) No. 156		Infliximab	Refractory uveoretinitis caused by Behcet's disease. Limited to cases in which existing treatments are not sufficiently effective.	Tanabe Seiyaku Co., Ltd.	Refractory uveoretinitis caused by Behcet's disease limited to cases in which existing treatments are not sufficiently effective	Mitsubishi Tanabe Pharma Corporation	2007/1/26	Remicade for IV infusion 100 mg	REMICADE® for IV Infusion100	infliximab (recombinant)			Approved
2002	2002/6/17	(14yaku) No. 157		Epoprostenol sodium	Pulmonary arterial hypertension excluding primary pulmonary hypertension	GlaxoSmithKline K.K.	Pulmonary arterial hypertension	GlaxoSmithKline K.K.	2004/6/22	Flolan for IV injection 0.5 mg Flolan for IV injection 1.5 mg	Flolan® for injection 0.5mg Flolan® for injection 1.5mg	Epoprostenol Sodium			Approved
2002	2002/10/2	(14yaku) No. 158	3	Nitric oxide	Improvement of hypoxemic respiratory failure in pulmonary hypertension. Use should be limited to newborns.	Ino Therapeutics Inc. Agent in Japan: Parexel International Corporation	Improvement of hypoxemic respiratory failure with accompanying pulmonary hypertension in newborns	Ino Therapeutics, LLC Air Water Co. is the exclusive manufacturing agent.	2008/7/16	Inoflo for inhalation 800 ppm	INOflo® for inhalation 800ppm	Nitric Oxide			Approved
2002	2002/10/2	(14yaku) No. 159		Imatinib mesylate	Gastrointestinal stromal tumor	Nihon Ciba-Geigy K.K.	KIT(CD117)-positive gastrointestinal stromal tumor	Novartis Pharma K.K.	2003/7/17	Glivec tablet 100 mg	Glivec® Tablets 100mg	Imatinib Mesylate			Approved
2002	2002/12/2	(14yaku) No. 160	3	Tacrolimus hydrate	Lupus nephritis	Fujisawa Pharmaceutical Co., Ltd.	Lupus nephritis limited to cases where steroids are not sufficiently effective or cannot be administered due to	Astellas Pharma Inc.	2007/1/26	Prograf capsule 0.5 mg Prograf capsule 1 mg	Prograf® Capsules 0.5mg Prograf®	Tacrolimus Hydrate			Approved
2002	2003/1/31	(15yaku) No. 161		Bosentan	Pulmonary arterial hypertension	Actelion Pharmaceuticals Japan Ltd.	Pulmonary arterial hypertension limited to World Health Organization (WHO) Class Ⅱ, Ⅲ and Ⅳ	Actelion Pharmaceuticals Japan Ltd.	2005/4/11 2012/11/21 (addition of Class Ⅱ of WHO criteria)	Tracleer tablet 62.5 mg	Tracleer® 62.5	Bosentan hydrate			Approved

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2003	2003/5/29	(15yaku) No. 162		Fluocinolone acetonide preparation for intraocular implantation	Uveitis extending to the posterior segment of the eye	Bausch & Lomb Japan	—	—	—	—	—	—			
2003	2003/06/17 2004/03/30 *16	(15yaku) No. 163 *16	2	Amiodarone hydrochloride	Recurrent life-threatening cardiac arrhythmias: ventricular fibrillation and hemodynamically unstable ventricular tachycardia	Taisho Pharmaceutical Co., Ltd., Taisho Sanofi-Synthélabo (currently Sanofi Aventis after Japan Winthrop Pharmaceutical), 2003-06-17 Sanofi-Synthélabo Corp. (currently Sanofi Aventis), 2004-03-30 *16	Refractory life-threatening refractory life-threatening cardiac arrhythmias limited to emergency cases: ventricular fibrillation and hemodynamically unstable ventricular tachycardia	Sanofi K.K.	2007/1/26	Ancaron injection 150 mg	Ancaron® inj. 150	Amiodarone Hydrochloride	Designation revoked (2004/03/30) *16		Approved
2003	2003/8/1	(15yaku) No. 164		Atazanavir sulfate	HIV Infection	Bristol	HIV-1 Infection	Bristol-Myers	2003/12/18	Reyataz capsule 150 mg Reyataz capsule 200 mg	REYATAZ CAPSULES 150mg REYATAZ CAPSULES 200mg	Atazanavir Sulfate			Approved
2003	2003/9/26	(15yaku) No. 165	1	Busulfan	Pretreatment for hematopoietic stem cell transplantation	Kirin Brewery Company, Limited	· Pretreatment for allogenic hematopoietic stem cell transplantation · Pretreatment for autologous hematopoietic stem cell transplantation for the Ewing sarcoma family of tumors and neuroblastoma	Otsuka Pharmaceutical Co., Ltd.	2006/07/26 2006/10/20 (Approval of the expanded age indication)	Busulfex for IV infusion 60 mg	Busulfex® injection	Busulfan			Approved
2003	2003/12/12	(15yaku) No. 166	1	Tenofovir disoproxil fumarate	HIV-1 Infection	Japan Tobacco, Inc.	HIV-1 Infection	Japan Tobacco, Inc.	2004/3/25	Viread tablet 300 mg Truvada combination tablet *HC1661 Stribild combination tablet *HC1662	Viread® Tab. 300mg Truvada® Combination Tab. Stribild® Combination Tab.	Tenofovir Disoproxil Fumarate			Approved
2003	2003/12/12	(15yaku) No. 167		Bortezomib	Relapsed or refractory multiple myeloma	Janssen Pharmaceutical K.K.	Multiple myeloma *24	Janssen Pharmaceutical K.K.	2006-10-20 2011-09-16 (new indication, new dosage) *24	Velcade for injection 3 mg	VELCADE® Injection	Bortezomib			Approved
2003	2004/3/22	(16yaku) No. 168		Argatroban	Heparin-induced thrombocytopenia (HIT): prophylaxis or treatment of thrombosis, anticoagulation during percutaneous coronary intervention (PCI) (including patients at risk of HIT) and prevention of coagulation of perfused blood during extracorporeal circulation (hemodialysis)	Mitsubishi Pharma Corporation Daiichi Pharmaceutical Co., Ltd.	Prevention of coagulation of blood during extracorporeal circulation in patients with heparin-induced thrombocytopenia (HIT) type II (hemodialysis), prevention of coagulation of blood in percutaneous coronary intervention (PCI) in patients with HIT type II (including patients at risk of HIT type II) and prophylaxis of thrombosis in patients with HIT type II	Mitsubishi Tanabe Pharma Corporation Daiichi-Sankyo Company, Limited	2008/07/16 2011/05/20 *17	Novastan HI injection 10 mg/2 mL Slonnon HI injection 10 mg/2 mL	Novastan® HI inj. 10mg/2mL SLONNON® HI INJECTION	Argatroban Hydrate			Approved
2004	2004/7/7	(16yaku) No. 169		Valganciclovir	Treatment of cytomegalovirus retinitis in patients with AIDS	Tanabe Seiyaku Co., Ltd.	Treatment of cytomegalovirus retinitis in patients with AIDS	Mitsubishi Tanabe Pharma Corporation	2004/11/5	Valixa Tablet 450 mg	VALIXA® Tablets 450mg	Valganciclovir Hydrochloride			Approved
2004	2004/7/7	(16yaku) No. 170		Pegaptanib sodium	Age-related macular degeneration with subfoveal choroidal neovascularization	Pfizer Japan Inc.	Age-related macular degeneration with subfoveal choroidal neovascularization	Pfizer Japan Inc.	2008/7/16	Macugen IVT injection	MACUGEN® IVT Inj. KIT 0.3mg	Pegaptanib sodium			Approved
2004	2004/07/07 2005/12/13 *18	(16yaku) No. 171 *18		Tacrolimus hydrate	Vernal conjunctivitis for which anti-allergic drugs are not sufficiently effective	2004-07-07 Fujisawa Pharmaceutical Co., Ltd. 2005-12-13 Senju Pharmaceutical Co., Ltd. *18	Vernal conjunctivitis for which anti-allergic drugs are not sufficiently effective	Astellas Pharma Inc. Senju Pharmaceutical Co., Ltd.	2008/1/25	Talymus ophthalmic suspension 0.1%	TALYMUS® OPHTHALMIC SUSPENSION 0.1%	Tacrolimus Hydrate			Approved
2004	2004/10/13	(16yaku) No. 172	1	Emtricitabine	HIV-1 Infection	Japan Tobacco, Inc.	HIV-1 Infection	Japan Tobacco, Inc.	2005/3/23	Emtriva capsule 200 mg Truvada combination tablet *HC1721 Stribild combination tablet *HC1722	Emtriva® Capsules 200mg Truvada® Combination Tab. Stribild® Combination Tab.	Emtricitabine			Approved

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2004	2004/10/13	(16yaku) No. 173		FTY720	Suppression of rejection after renal transplantation	Mitsubishi Pharma Corporation (currently Mitsubishi Tanabe Pharma Corporation) Novartis Pharma K.K.	—	—	—	—	—	—			
2004	2004/10/13	(16yaku) No. 174	2	Fosamprenavir calcium hydrate	HIV Infection	GlaxoSmithKline K.K.	HIV Infection	ViiV Healthcare K.K.	2004/12/24	Lexiva tablet 700 mg	LexIVa® Tablets 700	Fosamprenavir Calcium Hydrate			Approved
2004	2004/11/5	(16yaku) No. 175	3	NPC-02	Wilson's disease	Nobelpharma Co., Ltd.	Wilson's disease (hepatolenticular degeneration)	Nobelpharma Co., Ltd.	2008/1/25	Nobelzin capsule 25 mg Nobelzin capsule 50 mg	NOBELZIN® Capsules 25mg NOBELZIN® Capsules 50mg	Zinc acetate dihydrate			Approved
2004	2005/1/13	(17yaku) No. 176		Ibritumomab tiuxetan	CD20-positive B-cell non-Hodgkin's lymphoma	Nihon Schering K.K.	1. Relapsed or refractory CD20-positive disease in low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma (MCL) 2. Confirmation of the accumulation site of ibritumomab tiuxetan (recombinant)	Bayer Holding Ltd.	2008/1/25	1. Zevalin yttrium (⁹⁰Y) injection 2. Zevalin indium (¹¹¹In) injection	1. Zevalin® yttrium injection 2. Zevalin® indium injection	1. Ibritumomab Tiuxetan (recombinant) Yttrium Chloride (⁹⁰Y) 2. Ibritumomab Tiuxetan (recombinant) Indium Chloride (¹¹¹In)			Approved
2004	2005/2/8	(17yaku) No. 177		SOT-107	Glioma	Sosei Co., Ltd.	—	—	—	—	—	—	Designation revoked (2007/08/03)	2007/8/3	Revoked
2004	2005/2/8	(17yaku) No. 178		Thalidomide	Multiple myeloma limited to cases for which existing treatments are not sufficiently effective	Fujimoto Pharmaceutical Corporation	Relapsed or refractory multiple myeloma	Fujimoto Pharmaceutical Corporation	2008/10/16	Thaled capsule 50 mg Thaled capsule 100 mg	THALED® CAPSULE 50 THALED® CAPSULE 100	Thalidomide			Approved
2004	2005/3/24	(17yaku) No. 179	3	Phenobarbital sodium IV	Neonatal convulsions	Nobelpharma Co., Ltd.	Neonatal convulsions	Nobelpharma Co., Ltd.	2008/10/16	Nobelbar 250 mg for Injection	NOBELBAR® 250mg for Injection	Phenobarbital Sodium			Approved
2005	2005/6/20	(17yaku) No. 180		Edaravone	Amyotrophic lateral sclerosis (ALS)	Mitsubishi Pharma Corporation (currently Mitsubishi Tanabe Pharma Corporation)	—	—	—	—	—	Edaravone			
2005	2006/2/10	(18yaku) No. 181		Alglucosidase alfa	Glycogen storage disease type II	Genzyme Japan K.K.	Glycogen storage disease type II	Genzyme Japan K.K.	2007/4/18	Myozyme for IV infusion 50 mg	MYOZYME®	Alglucosidase Alfa (recombinant)			Approved
2005	2006/3/10	(18yaku) No. 182		Ranibizumab	Age-related macular degeneration with subfoveal choroidal neovascularization	Novartis Pharma K.K.	Age-related macular degeneration with subfoveal choroidal neovascularization	Novartis Pharma K.K.	2009/1/21	Lucentis solution for intravitreal injection 2.3 mg/0.23 mL	LUCENTIS® solution for intravitreal injection 2.3mg/0.23mL	Ranibizumab (recombinant)			Approved
2006	2006/5/8	(18yaku) No. 183		Doxorubicin hydrochloride liposome	AIDS-related Kaposi sarcoma	Janssen Pharmaceutical K.K.	AIDS-related Kaposi sarcoma	Janssen Pharmaceutical K.K.	2007/1/4	Doxil injection 20 mg	DOXIL® Injection	Doxorubicin Hydrochloride			Approved
2006	2006/6/9	(18yaku) No. 184	1	Precipitated H5N1 influenza vaccine	Prophylaxis of H5N1 influenza	Denka Seiken Co., Ltd.	Prophylaxis of H5N1 influenza	Denka Seiken Co., Ltd.	2013/3/25	H5N1 precipitated influenza vaccine "SEIKEN" 1 mL		Adsorbed Influenza Vaccine(H5N1)			Approved
2006	2006/6/9	(18yaku) No. 185	1	Precipitated H5N1 influenza vaccine	Prophylaxis of H5N1 influenza	Kitasato Institute	Prophylaxis of H5N1 influenza	Kitasato Daiichi Sankyo Vaccine Co., Ltd.	2007/10/19	H5N1 precipitated influenza vaccine "Kitasato Daiichi-Sankyo"		Adsorbed Influenza Vaccine(H5N1)			Approved
2006	2006/6/9	(18yaku) No. 186	1	Precipitated H5N1 influenza vaccine	Prophylaxis of H5N1 influenza	Research Institute for Microbial Diseases, Osaka University	Prophylaxis of H5N1 influenza	Research Foundation for Microbial Diseases of Osaka University BIKEN	2007/10/19	H5N1 precipitated influenza vaccine "BIKEN"		Adsorbed Influenza Vaccine(H5N1)			Approved
2006	2006/6/9	(18yaku) No. 187	2	Precipitated H5N1 influenza vaccine	Prophylaxis of H5N1 influenza	Kaketsuken	Prophylaxis of H5N1 influenza	Kaketsuken	2010/10/27	H5N1 precipitated influenza vaccine "Kaketsuken"		Adsorbed Influenza Vaccine(H5N1)			Approved
2006	2006/6/9	(18yaku) No. 188	2	Nelarabine	Relapsed or refractory T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) in adult and pediatric patients and adult T-cell leukemia-lymphoma	GlaxoSmithKline K.K.	Relapsed or refractory T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL)	GlaxoSmithKline K.K.	2007/10/19	Arranon G for IV injection 250 mg	Arranon G® Injection	Nelarabine			Approved
2006	2006/6/9	(18yaku) No. 189		Anecortave acetate	Age-related macular degeneration with subfoveal choroid neovascularization	Alcon Japan Ltd.	—	—	—	—	—	Anecortave acetate	Designation revoked (2010/03/04)	2010/3/4	Revoked
2006	2006/6/9	(18yaku) No. 190	2	Risedronate sodium hydrate	Paget's disease of bone	Ajinomoto Co. Inc. Takeda Pharmaceutical Co., Ltd.	Paget's disease of bone	Ajinomoto Co. Inc. Takeda Pharmaceutical Co., Ltd.	2008/7/16	Actonel tablet 17.5 mg Benet tablet 17.5 mg	Actonel® Tablet 17.5mg BENET® Tablets 17.5mg.	Risedronate Sodium Hydrate			Approved

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2006	2006/6/9	(18yaku) No. 191		Leuprorelin acetate	Spinal and bulbar muscular atrophy	Takeda Pharmaceutical Co., Ltd.	—	—	—	—	—	Leuprorelin Acetate			
2006	2006/08/11 2010/02/02 *21	(18yaku) No. 192		AMG531	Improvement of thrombocytopenia associated with chronic idiopathic thrombocytopenic purpura	Amgen Development K.K., 2006-08-11 Kyowa Hakko Kirin Co., Ltd., 2010-02-02	Chronic Idiopathic thrombocytopenic purpura	Kyowa Hakko Kirin Co., Ltd.	2011/1/21	Romiplate SC injection 250 μg for preparative purpose	Romiplate® for s.c. injection	Romiplostim (recombinant)			Approved
2006	2006/8/11	(18yaku) No. 193	3	Tolvaptan	Inhibition of progression of polycystic kidney disease	Otsuka Pharmaceutical Co., Ltd.	Prevention of the progression of autosomal dominant polycystic kidney disease accompanied by an already enlarged renal volume and a high rate of increase in renal volume	Otsuka Pharmaceutical Co., Ltd.	2014/3/24	Samsca tablets 7.5mg Samsca tablets 15mg Samsca tablets 30mg	Samsca® tablets 7.5mg Samsca® tablets 15mg Samsca® tablets 30mg	Tolvaptan			Approved
2006	2006/12/14	(18yaku) No. 194		Idursulfase	Mucopolysaccharidosis II	Genzyme Japan K.K.	Mucopolysaccharidosis II	Genzyme Japan K.K.	2007/10/4	Elaprase for IV infusion 6 mg	ELAPRASE®	Idursulfase (recombinant)			Approved
2006	2007/1/25	(19yaku) No. 195		Darunavir ethanolate	HIV Infection in patients previously treated with anti-HIV agents	Janssen Pharmaceutical K.K.	HIV Infection *19	Janssen Pharmaceutical K.K.	2007/11/22 2009/10/16 *19	Prezista tablet 300 mg Prezistanaive tablet 400 mg	PREZISTANAIVE® Tablets PREZISTA® Tablets	Darunavir Ethanolate			Approved
2006	2007/2/27	(19yaku) No. 196		Sildenafil citrate	Pulmonary arterial hypertension	Pfizer Japan Inc.	Pulmonary arterial hypertension	Pfizer Japan Inc.	2008/1/25	Revatio tablet 20 mg	Revatio® Tablets 20mg	Sildenafil Citrate			Approved
2006	2007/3/23	(19yaku) No. 197	3	SB-497115-GR	Improvement of thrombocytopenia in chronic idiopathic thrombocytopenic purpura	GlaxoSmithKline K.K.	Chronic idiopathic thrombocytopenic purpura	GlaxoSmithKline K.K.	2010/10/27	Revolade tablet 12.5 mg Revolade tablet 25 mg	Revolade® Tablets 12.5mg Revolade® Tablets 25mg	Eltrombopag Olamine			Approved
2006	2007/3/23	(19yaku) No. 198		Nilotinib hydrochloride hydrate	Chronic myelogenous leukemia (CML) with resistance or intolerance to imatinib mesylate, relapsed or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)	Novartis Pharma K.K.	Chronic myelogenous leukemia (CML) with resistance to imatinib or accelerated-phase CML	Novartis Pharma K.K.	2009/1/21	Tasigna capsule 150 mg Tasigna capsule 200 mg	Tasigna® Capsules 150mg Tasigna® Capsules 200mg	Nilotinib Hydrochloride Hydrate			Approved
2006	2007/3/23	(19yaku) No. 199		Dasatinib hydrate	Chronic myelogenous leukemia (CML) with resistance or intolerance to imatinib mesylate, relapsed or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)	Bristol-Myers	Chronic myelogenous leukemia (CML) with resistance to imatinib, relapsed or refractory Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)	Bristol-Myers	2009/1/21	Sprycel tablet 20 mg Sprycel tablet 50 mg	Sprycel® Tablets 20mg Sprycel® Tablets 50mg	Dasatinib Hydrate			Approved
2007	2007/5/16	(19yaku) No. 200	3	Ambrisentan	Pulmonary arterial hypertension	GlaxoSmithKline K.K.	Pulmonary arterial hypertension	GlaxoSmithKline K.K.	2010/7/23	Volibris tablet 2.5 mg	Volibris® Tablets 2.5mg	Ambrisentan			Approved
2007	2007/6/5	(19yaku) No. 201	1	Galsulfase (recombinant)	Mucopolysaccharidosis VI	AnGes MG, Inc.	Mucopolysaccharidosis VI	AnGes MG, Inc.	2008/3/28	Naglazyme for IV infusion 5 mg	Naglazyme®	Galsulfase (recombinant)			Approved
2007	2007/9/13	(19yaku) No. 202	1	Sapropterin hydrochloride	Reduction of serum phenylalanine (Phe) levels in hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylalanine hydroxylase deficiency (BH4-responsive HPA)	Asubio Pharma Co., Ltd.	Reduction of serum phenylalanine (Phe) levels in hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylalanine hydroxylase deficiency (BH4-responsive HPA)	Daiichi Sankyo Company, Limited	2008/7/16	Biopten granule 2.5%	BIOPTEN® GRANULES 2.5%	Sapropterin Hydrochloride			Approved
2007	2007/9/13	(19yaku) No. 203		FTY720	Prevention of recurrence and inhibition of progression of multiple sclerosis	Mitsubishi Pharma Corporation Novartis Pharma K.K.	Prevention of relapse and delay of physical disability progression in multiple sclerosis	Mitsubishi Tanabe Pharma Corporation Novartis Pharma K.K.	2011/9/26	Imusera capsule 0.5 mg Gilenya capsule 0.5 mg	IMUSERA® Capsules 0.5mg Gilenya® Capsules 0.5mg	Fingolimod Hydrochloride			Approved
2007	2007/11/26	(19yaku) No. 204		Raltegravir potassium	HIV-1 Infection	Banyu Pharmaceutical Co., Ltd.	HIV Infection	MSD K.K.	2008/6/24	Isentress tablet 400 mg	ISENTRESS® Tablets 400mg	Raltegravir Potassium			Approved
2007	2008/2/18	(20yaku) No. 205	1	OPC-67683	Pulmonary tuberculosis	Otsuka Pharmaceutical Co., Ltd.	<Indicated bacteria> Mycobacterium tuberculosis susceptible to delamanid <Indication> Pulmonary multidrug-resistant tuberculosis (MDR-TB)	Otsuka Pharmaceutical Co., Ltd.	2014/7/4	Deltyba tablets 50mg	DELTYBA® tablets 50mg	Delamanid			Approved
2007	2008/2/18	(20yaku) No. 206		CC-5013 lenalidomide	Relapsed or refractory multiple myeloma limited to previously treated patients	Celgene K.K.	Relapsed or refractory multiple myeloma	Celgene K.K.	2010/6/25	Revlimid capsule 5 mg	Revlimid® Capsules 5mg	Lenalidomide Hydrate			Approved

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2007	2008/2/18	(20yaku) No. 207		CC-5013 lenalidomide	Anemia due to low- or intermediate-1-risk myelodysplastic syndrome with deletion of 5(q31-33) with or without other additional genetic abnormalities	Celgene K.K.	Myelodysplastic syndrome with deletion on the long arm of chromosome 5	Celgene K.K.	2010/8/20	Revlimid capsule 5 mg	Revlimid® Capsules 5mg	Lenalidomide Hydrate			Approved
2008	2008/5/20	(20yaku) No. 208	1	Natalizumab	Inhibition of progression or prevention of relapse of relapsinging form of multiple sclerosis on monotherapy	Biogen Idec Japan Ltd.	Prevention of relapse and delay of physical disability progression in multiple sclerosis	Biogen Idec Japan Ltd.	2014/3/24	Tysabri for I.V. infusion 300mg	Tysabri® for I.V. Infusion	Natalizumab (Genetical Recombination)			Approved
2008	2008/6/6	(20yaku) No. 209		Infliximab (recombinant)	Ankylosing spondylitis	Mitsubishi Tanabe Pharma Corporation	Ankylosing spondylitis for which existing treatments are not sufficiently effective	Mitsubishi Tanabe Pharma Corporation	2010/4/16	Remicade for IV infusion 100 mg	REMICADE® for IV Infusion100	Infliximab (recombinant)			Approved
2008	2008/6/6	(20yaku) No. 210		Tacrolimus hydrate	Myasthenia gravis (excluding generalized myasthenia gravis when post-thymectomy steroid treatment is not sufficiently effective or it cannot be administered due to adverse drug reactions) *20	Astellas Pharma Inc.	Myasthenia gravis *20	Astellas Pharma Inc.	2009/10/16 *20	Prograf capsule 0.5 mg Prograf capsule 1 mg Prograf granule 0.2 mg Prograf granule 1 mg	Prograf® Capsules 0.5mg Prograf® Capsules 1mg Prograf® Granules 0.2mg Prograf® Granules 1mg	Tacrolimus Hydrate			Approved
2008	2008/06/06 2011/11/16 *26	(20yaku) No. 211	3	UMN-0501 (influenza HA recombinant vaccine for H5N1) ASP7373 (influenza HA recombinant vaccine for H5N1)	Prophylaxis of H5N1 influenza	UMN Pharma Inc. Astellas Pharma Inc. *26	—	—	—	—	—	—	Designation revoked (2011/11/16) *26		
2008	2008/6/6	(20yaku) No. 212	2	Forodesine hydrochloride	Relapsed or refractory cases of peripheral T-cell lymphoma, adult T-cell leukemia/lymphoma, cutaneous T-cell lymphoma, T-cell acute lymphocytic leukemia/T-cell lymphoblastic lymphoma	Mundipharma K.K.	—	—	—	—	—	Forodesine hydrochloride			
2008	2008/8/4	(20yaku) No. 213		Maraviroc	CCR5-tropic HIV-1 infection	Pfizer Japan Inc.	CCR5-tropic HIV-1 Infection	ViiV Healthcare K.K.	2008/12/15	Celsentri tablet 150 mg	Celsentri® Tablets	Maraviroc			Approved
2008	2008/8/4	(20yaku) No. 214		Etravirine	HIV-1 infection	Janssen Pharmaceutical K.K.	HIV-1 infection	Janssen Pharmaceutical K.K.	2008/12/25	Intelence tablet 100 mg	INTELENCE® Tablets	Etravirine			Approved
2008	2008/9/12	(20yaku) No. 215	3	GSK1557484A (pandemic H5N1 influenza virus vaccine with adjuvant added prior to use)	Prophylaxis of H5N1 influenza	GlaxoSmithKline K.K.	—	—	—	—	—	—			
2008	2008/09/12 2011/07/11 *25	(20yaku) No. 216		Sodium phenylbutyrate	Urea cycle disorders	Ucyclyd Pharma, Inc., 2008-09-12 CMIC Co., Ltd., 2011-07-11 *25	Urea cycle disorders	Orphan Pacific, Inc.	2012/9/28	Buphenyl tablet 500 mg Buphenyl Granule 94%	Buphenyl® Tablets 500mg Buphenyl® Granules 94%	Sodium Phenylbutyrate			Approved
2008	2008/11/17	(20yaku) No. 217		Azacitidine	Myelodysplastic syndrome	Nippon Shinyaku Co., Ltd.	Myelodysplastic syndrome	Nippon Shinyaku Co., Ltd.	2011/1/21	Vidaza for injection 100 mg	Vidaza® for Injection 100mg	Azacitidine			Approved
2008	2008/12/11	(20yaku) No. 218		Dried sulfonated human immunoglobulin	Improvement of neuropathy in Churg-Strauss syndrome and allergic granulomatous angiitis (limited to cases for which steroid treatment is not sufficiently effective)	Kaketsuken, Teijin Pharma Limited	Improvement of neuropathy in Churg-Strauss syndrome and allergic granulomatous angiitis (limited to cases for which steroid treatment is not sufficiently effective)	Kaketsuken	2010/1/20	Kenketsu Venilon-I for IV injection 500 mg Kenketsu Venilon-I for IV injection 1000 mg Kenketsu Venilon-I for IV injection 2500 mg Kenketsu Venilon-I for IV injection 5000 mg	Kenketsu Venilon®-I Kenketsu Venilon®-I Kenketsu Venilon®-I Kenketsu Venilon®-I	Freeze-dried Sulfonated Normal Human Immunoglobulin			Approved

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2008	2008/12/15	(20yaku) No. 219		Talaporfin Sodium	Enhancement of light sensitivity in photodynamic therapy for malignant glioma	Meiji Seika Kaisha, Ltd.	Primary malignant brain tumor limited to cases treated with resection	Meiji Seika Pharma Co., Ltd.	2013/9/20	Leserphyrin for injection 100 mg	LASERPHYRIN® FOR INJECTION	Talaporfin Sodium	Designation revoked (2013/08/12) Designation was transferred to (25yaku) No. 309 with the change in indication from malignant glioma to malignant brain tumor.	2013/8/12	Revoked
2008	2008/12/22	(20yaku) No. 220		Eculizumab	Paroxysmal nocturnal hemoglobinuria	Alexion Pharmaceuticals, Inc.	Inhibition of hemolysis due to paroxysmal nocturnal hemoglobinuria	Alexion Pharmaceuticals, Inc.	2010/4/16	Soliris for IV infusion 300 mg	Soliris®	Eculizumab (recombinant)			Approved
2008	2009/2/9	(21yaku) No. 221	4	MC710 (freeze dried human blood coagulation factor X added to activated blood coagulation factor VII)	Inhibition of bleeding in patients with congenital hemophilia who have inhibitors to blood coagulation factor VIII or IX	Kaketsuken	—	—	—	—	—	—	Designation revoked (2014/05/13) Designation was transferred to (26yaku) No. 337 with the change in indication from Inhibition of bleeding in patients with hemophilia who have inhibitors to blood coagulation factor VIII or IX	2014/5/13	Revoked
2008	2009/2/9	(21yaku) No. 222	3	SUN11031	Increase in the amount of food intake in anorexia nervosa (restricting type) or eating disorder not otherwise specified (insufficient food intake, low body weight, and no binging or purging)	Asubio Pharmaceuticals, Inc. (currently Daiichi Pharmaceutical Co., Ltd.)	—	—	—	—	—	—	Designation revoked (2012/05/11)	2012/5/11	Revoked
2008	2009/3/10 2014/10/16*	(21yaku) No. 223	4	Glatiramer acetate	Reduction of recurrence frequency in relapsing-remitting multiple sclerosis (MS)	Teva Pharmaceutical K.K.,2009-03-10 Takeda Pharmaceutical Co., Ltd., 2014-10-16 *	—	—	—	—	—	Glatiramer Acetate			
2009	2009/5/12	(21yaku) No. 224		Levodopa-carbidopa formulation for duodenal administration	1. Parkinson's disease with severe mobility complications (Hoehn & Yahr severity stage IV or V, with wearing-off, no on/delayed on, or on-off phenomena, dyskinesia) when conventional oral therapy is not sufficiently effective 2. Parkinson's disease at Hoehn & Yahr severity stage I, II or III, but limited to cases where gastrostomy has already been performed due to dysphagia or for other reasons so that oral therapy is difficult	Solvay Pharmaceuticals, Inc. (currently AbbVie)	—	—	—	—	—	Levodopa Carbidopa Hydrate			
2009	2009/6/5	(21yaku) No. 225	3	Preparation for implanting carmustine in the brain	FIP1L1-PDGFR α-positive hypereosinophilic syndrome and chronic eosinophilic leukemia	Eisai Co., Ltd.	Malignant glioma	Nobelpharma Co., Ltd.	2012/9/28	Gliadel intracerebral implant 7.7 mg	Gliadel® 7.7mg Implant	Carmustine			Approved
2009	2009/9/11	(21yaku) No. 226		Polyethylene glycol-treated human immunoglobulin	Generalized myasthenia gravis when post-thymectomy treatment with steroidal or non-steroidal immunosuppressive agents is not sufficiently effective	Benesis Corporation	Generalized myasthenia gravis when post-thymectomy treatment with steroidal or non-steroidal immunosuppressive agents is not sufficiently effective	Japan Blood Products Organization	2011/9/26	Venoglobulin IH 5% IV injection 0.5 g/10 mL Venoglobulin IH 5% IV injection 1 g/20 mL Venoglobulin IH 5% IV injection 2.5 g/50 mL Venoglobulin IH 5% IV injection 5 g/100 mL	Venoglobulin® IH5%IV0.5g/10mL Venoglobulin® IH5%IV1g/20mL Venoglobulin® IH5%IV2.5g/50mL Venoglobulin® IH5%IV5g/100mL	Polyethylene Glycol-treated Normal Human Immunoglobulin			Approved

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2009	2009/10/28	(21yaku) No. 227		Bendamustine hydrochloride	Relapsed or refractory cases of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma (MCL)	SymBio Pharmaceuticals Limited	Relapsed or refractory cases of low-grade B-cell non-Hodgkin's lymphoma and mantle cell lymphoma (MCL)	SymBio Pharmaceuticals Limited	2010/10/27	Treakisym for IV infusion 100 mg	TREAKISYM® Injection 100mg	Bendamustine Hydrochloride			Approved
2010	2010/6/16	(22yaku) No. 228		Vorinostat	Cutaneous T-cell lymphoma	Banyu Pharmaceutical Co., Ltd.	Cutaneous T-cell lymphoma	MSD K.K.	2011/7/1	Zolinza capsule 100 mg	Zolinza® Capsules 100mg	Vorinostat			Approved
2010	2010/06/16 2011/06/10 *22	(22yaku) No. 229		BLB-750 (H5N1 cell culture influenza vaccine)	Prophylaxis of H5N1 influenza	Baxter, 2010-06-16 Takeda Pharmaceutical Co., Ltd., 2011-06-10 *22	Prophylaxis of H5N1 influenza	Baxter Takeda Pharmaceutical Co., Ltd.	2013/6/26	H5N1 cell culture influenza vaccine "Baxter" H5N1 cell culture influenza vaccine "Takeda"	—	Cell culture influenza vaccine (strain H5N1)			Approved
2010	2010/6/16	(22yaku) No. 230	3, 1 *28	Midismase (recombinant) *28	Idiopathic pulmonary fibrosis *28	LTT Bio-Pharma Co., Ltd.	—	—	—	—	—	Midismase (recombinant)			
2010	2010/8/11	(22yaku) No. 231		Canakinumab	Cryopyrin-associated periodic syndrome in patients ≥2 years of age: familial cold autoinflammatory syndrome, Muckle - Wells syndrome, neonatal onset multi-organ inflammatory disease	Novartis Pharma K.K.	Cryopyrin-associated periodic syndrome in patients ≥2 years of age: familial cold autoinflammatory syndrome, Muckle - Wells syndrome, neonatal onset multi-organ inflammatory disease	Novartis Pharma K.K.	2011/9/26	Ilaris for s.c. injection 150 mg	Ilaris® for s.c. injection 150mg	Canakinumab (recombinant)			Approved
2010	2010/8/11	(22yaku) No. 232	1, 3 *27	KW-0761	CCR4-positive adult T-cell leukemia/lymphoma *27	Kyowa Hakko Kirin Co., Ltd.	CCR4-positive adult T-cell leukemia/lymphoma *27	Kyowa Hakko Kirin Co., Ltd.	2012/03/30 2014/12/18 *27	Poteligeo for IV infusion 20 mg	POTELIGEO® Injection	Mogamulizumab (recombinant)			Approved
2010	2010/9/14 2012/7/4 ※31	(22yaku) No. 233	3	5-Aminolevulinic acid hydrochloride	Visualization of tumor tissue during surgical resection of malignant glioma	Nobelpharma Co., Ltd. SBI Pharmaceuticals Co., Ltd. ※31	Visualization of tumor tissue during surgical resection of malignant glioma	Nobelpharma Co., Ltd. SBI Pharmaceuticals Co., Ltd. ※31	2013/3/25	Alabel oral 1.5 g Alaglio oral 1.5 g	Alabel® Oral 1.5g	Aminolevulinic acid hydrochloride			Approved
2010	2010/11/10	(22yaku) No. 234		Bortezomib	Onset of multiple myeloma	Janssen Pharmaceutical K.K.	Multiple myeloma *24	Janssen Pharmaceutical K.K.	2011/9/16 ※24	Velcade for injection 3 mg	VELCADE® Injection	Bortezomib			Approved
2010	2010/11/10	(22yaku) No. 235		Bortezomib	Mantle cell lymphoma	Janssen Pharmaceutical K.K.	—	—	—	—	—	Bortezomib			
2010	2010/11/10	(22yaku) No. 236	1	Colistin sodium methanesulfonate	Indicated bacterial strains: Multidrug-resistant Pseudomonas aeruginosa (MDRP), multidrug-resistant Acinetobacter and other multidrug-resistant Gram-negative bacteria that are sensitive to this drug Indications: Various infectious diseases	GlaxoSmithKline K.K.	[Indicated bacteria] Colistin-susceptible bacteria: Escherichia coli, Citrobacter species, Klebsiella species, Enterobacter species, P. aeruginosa, Acinetobacter spp., In this regard, the bacteria that showed resistance for another antibacterial drugs [Indications] Infection diseases of varied type	GlaxoSmithKline K.K.	2015/3/26	Aldreb for Intravenous Injection 150mg	Aldreb® for Intravenous Injection 150mg	Colistin sodium methanesulfonate			Approved
2010	2010/11/10 2014/12/4 *	(22yaku) No. 237	3 *29	GSK2402968 Drisapersen *	Duchenne muscular dystrophy	GlaxoSmithKline K.K. Prosensa holding N.V *	—	—	—	—	—	—			
2010	2011/1/28	(22yaku) No. 238		Crizotinib	ALK fusion gene-positive advanced non-small cell lung cancer	Pfizer Japan Inc.	Unresectable progressive or recurrent *ALK* fusion gene-positive non-small cell lung cancer	Pfizer Japan Inc.	2012/3/30	Xalkori capsule 200 mg Xalkori capsule 250 mg	XALKORI® Capsules 200mg XALKORI® Capsules 250mg	Crizotinib			Approved
2010	2011/3/9	(23yaku) No. 239		Stiripentol	Combination therapy with clobazam and sodium valproate to assist infants with clonic or tonic-clonic seizures in severe myoclonic epilepsy (Dravet syndrome) when these seizures are not sufficiently controlled by clobazam and sodium valproate.	Meiji Seika Kaisha, Ltd.	Used in combination with clobazam and sodium valproate for tonic-clonic seizures or clonic seizure syndrome, for which clobazam and sodium valproate are not sufficiently effective, in patients with Dravet syndrome.	Meiji Seika Pharma Co., Ltd.	2012/9/28	Diacomit dry syrup 250 mg Diacomit dry syrup 500 mg Diacomit capsule 250 mg	DIACOMIT DRYSYRUP250mg DIACOMIT DRYSYRUP500mg DIACOMIT CAPSULES250mg	Stiripentol			Approved

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2010	2011/3/9	(23yaku) No. 240		Apomorphine hydrochloride hydrate	Rescue therapy for diurnal variation in symptoms of Parkinson's disease when usual drug therapy is not sufficiently effective.	Kyowa Hakko Kirin Co., Ltd.	Improvement of "off" symptoms in Parkinson's disease (when frequent administration of levodopa-containing preparations or increasing the dose of other antiparkinsonian agents is not sufficiently effective)	Kyowa Hakko Kirin Co., Ltd.	2012/3/30	Apokyn SC injection 30 mg	Apokyn® subcutaneous injection	Apomorphine Hydrochloride Hydrate			Approved
2010	2011/3/9	(23yaku) No. 241		Genz-112638	Type 1 Gaucher disease	Genzyme Japan K.K.	Improvement of various symptoms of Gaucher disease (anemia, thrombocytopenia, hepatosplenomegaly, and bone manifestations)	Genzyme Japan K.K.	2015/3/26	Cerdelga capsule 100 mg	CERDELGA®capsule	Eliglustat tartrate			Approved
2010	2011/3/9	(23yaku) No. 242		Miglustat	Niemann-Pick disease type C	Actelion Pharmaceuticals Japan Ltd.	Niemann-Pick disease type C	Actelion Pharmaceuticals Japan Ltd.	2012/3/30	Brazaves capsule 100 mg	BRAZAVES® 100 mg	Miglustat			Approved
2011	2011/5/13 2013/4/4 ※30	(23yaku) No. 243		Velaglucerase alfa	Improvement of various symptoms of Gaucher disease (anemia, thrombocytopenia, hepatosplenomegaly, and bone manifestations)	Shire Human Genetic Therapies, Inc., 2011-05-13 Shire Japan KK, 2013-04-04 *30	Improvement of various symptoms of Gaucher disease (anemia, thrombocytopenia, hepatosplenomegaly, and bone manifestations)	Shire Japan KK	2014/7/4	VPRIV Injection 400 U	VPRIV® Injection 400 U	Velaglucerase Alfa (Genetical Recombination)	Designation revoked (2013/04/04) *30		Approved
2011	2011/6/10	(23yaku) No. 244		Dornase alfa (recombinant)	Improvement of lung function in cystic fibrosis	Chugai Pharmaceutical Co., Ltd.	Improvement of lung function in cystic fibrosis	Chugai Pharmaceutical Co., Ltd.	2012/3/30	Pulmozyme inhalation liquid 2.5 mg	PULMOZYME® Inhalation Solution 2.5mg	Dornase Alfa (recombinant)			Approved
2011	2011/6/10	(23yaku) No. 245	3	Trabectedin	Malignant soft tissue tumors with chromosomal translocation	Taiho Pharmaceutical Co., Ltd.	—	—	—	—	—	—			
2011	2011/6/10	(23yaku) No. 246		Sunitinib malate	Incurable unresectable pancreatic endocrine tumor	Pfizer Japan Inc.	Pancreatic neuroendocrine tumor	Pfizer Japan Inc.	2012/8/10	Sutent capsule 12.5 mg	SUTENT® Capsule	Sunitinib Malate			Approved
2011	2011/6/10	(23yaku) No. 247	1	Rufinamide	Combination therapy with antiepileptic drugs for tonic and atonic seizures in Lennox-Gastaut syndrome (age 4 or over)	Eisai Co., Ltd.	Combination therapy with antiepileptic drugs (AEDs) for tonic and atonic seizures in Lennox-Gastaut syndrome for which other AEDs are not sufficiently effective	Eisai Co., Ltd.	2013/3/25	Inovelon tablet 100 mg Inovelon tablet 200 mg	Inovelon®	Rufinamide			Approved
2011	2011/8/8	(23yaku) No. 248	3	Caffeine citrate	Primary apnea in premature and low birth weight infants (apnea of prematurity)	Nobelpharma Co., Ltd.	Primary apnea in premature and low birth weight infants (apnea of prematurity)	Nobelpharma Co., Ltd.	2014/3/24	Respia injection or oral solution 60mg	Respia®	Anhydrous Caffeine			Approved
2011	2011/9/8	(23yaku) No. 249		Ruxolitinib	Myelofibrosis	Novartis Pharma K.K.	Myelofibrosis	Novartis Pharma K.K.	2014/7/4	Jakavi tablets 5mg	JAKAVI® Tablets 5mg	Ruxolitinib Phosphate			Approved
2011	2011/9/8	(23yaku) No. 250	2 ※34	Ofatumumab (recombinant)	Chronic lymphocytic leukemia	GlaxoSmithKline K.K.	Relapsed or refractory CD20-positive chronic lymphocytic leukemia ※34	GlaxoSmithKline K.K.	2013/3/25 ※34	Arzerra for IV infusion 100 mg Arzerra for IV infusion 1000 mg	Arzerra®	Ofatumumab (recombinant)			Approved
2011	2011/9/8	(23yaku) No. 251	1	Tetrabenazine	Chorea associated with Huntington's disease	Alfresa Pharma Corporation	Chorea associated with Huntington's disease	Alfresa Pharma Corporation	2012/12/25	Choreazine tablet 12.5 mg	CHOREAZINE® Tablets 12.5mg	Tetrabenazine			Approved
2011	2011/9/8	(23yaku) No. 252		Riociguat	Chronic thromboembolic pulmonary hypertension	Bayer Holding Ltd.	Unresectable or postoperative residual/recurrence Chronic thromboembolic pulmonary hypertension	Bayer Holding Ltd.	2014/1/17	Adempas tablet 0.5mg Adempas tablet 1.0mg Adempas tablet 2.5mg	Adempas®	Riociguat			Approved
2011	2011/9/8	(23yaku) No. 253		Hemin	Acute porphyria attacks	CMIC Co., Ltd.	Symptom relief during acute porphyria attacks	OrphanPacific, Inc.	2013/3/25	Normosang for IV infusion 250 mg	Normosang®	Hemin			Approved
2011	2011/9/8	(23yaku) No. 254		BIBF 1120	Idiopathic pulmonary fibrosis	Nippon Boehringer Ingelheim Co., Ltd.	—	—	—	—	—	—			
2011	2011/11/16	(23yaku) No. 255		Rilpivirine hydrochloride	HIV-1 infection	Janssen Pharmaceutical K.K.	HIV-1 infection	Janssen Pharmaceutical K.K.	2012/5/18	Edurant tablet 25 mg	EDURANT® Tablets 25mg	Rilpivirine Hydrochloride			Approved
2011	2011/11/16	(23yaku) No. 256	2	Streptozocin	Pancreatic and gastrointestinal neuroendocrine tumors	Nobelpharma Co., Ltd.	Pancreatic and gastrointestinal neuroendocrine tumors	Nobelpharma Co., Ltd.	2014/9/26	Zanosar IV infusion 1g	ZANOSAR ®	Streptozocin			Approved
2011	2011/11/16	(23yaku) No. 257		Pazopanib hydrochloride	Progressive malignant soft tissue tumors	GlaxoSmithKline K.K.	Malignant soft tissue tumors	GlaxoSmithKline K.K	2012/9/28	Votrient tablet 200 mg	Votrient® Tablets 200mg	Pazopanib Hydrochloride			Approved
2011	2011/12/14	(23yaku) No. 258		Everolimus	Tuberous sclerosis	Novartis Pharma K.K.	Renal angiomyolipoma associated with tuberous sclerosis (only for tablet preparations) Subependymal giant cell astrocytoma associated with tuberous sclerosis	Novartis Pharma K.K.	2012/11/21 (tablet) 2012/12/25 (dispersible tablet)	Afinitor tablet 2.5 mg Afinitor tablet 5 mg Afinitor dispersible tablet 2 mg Afinitor dispersible tablet 3 mg	AFINITOR® tablets dispersible® tablets	Everolimus			Approved
2011	2011/12/14	(23yaku) No. 259		Tafamidis meglumine	Transthyretin amyloid polyneuropathy (familial amyloid polyneuropathy)	Pfizer Japan Inc.	—	—	—	—	—	Tafamidis meglumine			

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2011	2011/12/14	(23yaku) No. 260		Thalidomide	Erythema nodosum leprosum	Fujimoto Pharmaceutical Corporation	Erythema nodosum leprosum	Fujimoto Pharmaceutical Corporation	2012/5/25	Thaled capsule 50 mg Thaled capsule 100 mg	THALED®CAPSULE 50 THALED®CAPSULE 100	Thalidomide			Approved
2011	2011/12/14	(23yaku) No. 261		Imatinib mesylate	FIP1L1-PDGFR α-positive hypereosinophilic syndrome and chronic eosinophilic leukemia	Novartis Pharma K.K.	FIP1L1-PDGFR α-positive hypereosinophilic syndrome and chronic eosinophilic leukemia	Novartis Pharma K.K.	2012/2/22	Glivec tablet 100mg	Glivec® Tablets 100mg	Imatinib Mesylate			Approved
2011	2012/2/15	(24yaku) No. 262		Pasireotide pamoate	Cushing's disease	Novartis Pharma K.K.	—	—	—	—	—	—			
2011	2012/3/19	(24yaku) No. 263		Imatinib mesylate	Pulmonary arterial hypertension	Novartis Pharma K.K.	—	—	—	—	—	Imatinib Mesylate			
2011	2012/3/19	(24yaku) No. 264	1	Betaine anhydrous	Adjunctive therapy for homocystinuria with deficiencies or abnormalities in cystathione β synthase (CBS), 5,10-methylenetetrahydrofolate reductase (MTHFR), or	ReqMed Company, Ltd.	homocystinuria	ReqMed Company, Ltd.	2014/1/17	Cystadane powder	Cystadane® Powder	Betaine			Approved
2011	2012/3/19	(24yaku) No. 265		Z-521	Hypophosphatemia with rickets or osteomalacia	Zeria Pharmaceutical Co., Ltd.	Hypophosphatemia	Zeria Pharmaceutical Co., Ltd.	2012/12/25	Phosribbon combination granule	Phosribbon® Combination Granules	Monobasic sodium phosphate monohydrate			Approved
2011	2012/3/19	(24yaku) No. 266		Clofarabine	Relapsed or refractory acute lymphocytic leukemia	Genzyme Japan K.K.	Relapsed or refractory acute lymphocytic leukemia	Sanofi K.K.	2013/3/25	Evoltra for IV infusion 20 mg	EVOLTRA®	Clofarabine			Approved
2011	2012/3/19	(24yaku) No. 267		Brentuximab vedotin	CD30-positive Hodgkin's lymphoma and anaplastic large cell lymphoma	Takeda Pharmaceutical Co., Ltd. Takeda Bio Development Center Limited	CD30-positive Hodgkin's lymphoma and anaplastic large cell lymphoma	Takeda Pharmaceutical Co., Ltd.	2014/1/17	Adetris for IV infusion 50mg	ADCETRIS®	Brentuximab Vedotin (recombinant)			Approved
2011	2012/3/19	(24yaku) No. 268		Recombinant von Willebrand factor (Rvwf)	Reduction of bleeding tendency in patients with von Willebrand disease	Baxter	—	—	—	—	—	—			
2011	2012/3/19	(24yaku) No. 269		Rurioctocog alfa (recombinant)	Reduction of bleeding tendency in patients with von Willebrand disease with decreased plasma concentration of blood coagulation factor VIII through plasma supplementation with blood coagulation factor VIII	Baxter	—	—	—	—	—	Rurioctocog alfa (recombinant)			
2012	2012/5/11	(24yaku) No. 270	2	Interferon gamma-1a (recombinant)	Mycosis fungoides (not during visceral dissemination stage) and Sézary syndrome	Shionogi & Co., Ltd.	Mycosis fungoides, Sézary syndrome	Shionogi & Co., Ltd.	2014/5/23	Imunomax-γ for Injection 50 Imunomax-γ for Injection 100	Imunomax®	Interferon Gamma-1a (Genetical Recombinationt)			Approved
2012	2012/5/11	(24yaku) No. 271	2	MPR-1020	Nephropathic cystinosis	Mylan Seiyaku Ltd.	Nephropathic cystinosis	Mylan Seiyaku Ltd.	2014/7/4	Nicystagon capsule 50mg Nicystagon capsule 100mg	Nicystagon® Capsules	Cysteamine Bitartrate			Approved
2012	2012/5/11	(24yaku) No. 272	2	Eprodisate disodium	AA amyloidosis	C. T. Development Swiss Corp. (currently A. T. Development Swiss Corp.)	—	—	—	—	—	—			
2012	2012/6/13	(24yaku) No. 273		Bendamustine hydrochloride	Chronic lymphocytic leukemia	SymBio Pharmaceuticals Limited	—	—	—	—	—	Bendamustine Hydrochloride			
2012	2012/6/13	(24yaku) No. 274		Type A influenza HA vaccine emulsion cell culture (H5N1 strain)	Prophylaxis of H5N1 influenza	Kaketsuken	Prophylaxis of H5N1 influenza	Kaketsuken	2014/3/24	—	—	Type A influenza HA vaccine emulsion cell culture (H5N1 strain)			Approved
2012	2012/6/13	(24yaku) No. 275		Type A influenza HA vaccine emulsion cell culture (prototype	Prophylaxis for new strains of influenza	Kaketsuken	Prophylaxis for pandemic influenza	Kaketsuken	2015/3/26	—	—	Type A influenza HA vaccine emulsion cell culture (prototype vaccine)			Approved
2012	2012/6/13	(24yaku) No. 276		Miglustat Hydrochloride	Fabry's disease	GlaxoSmithKline K.K.	—	—	—	—	—	—			
2012	2012/6/13	(24yaku) No. 277		Metreleptin	Treatment of diabetes or dyslipidemia due to lipoatrophy	Shionogi & Co., Ltd.	Lipoatrophy	Shionogi & Co., Ltd.	2013/3/25	Metreleptin for SC injection "Shionogi" 11.25 mg	Metreleptin	Metreleptin (recombinant)			Approved

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2012	2012/8/16	(24yaku) No. 278	2	Ecallantide	Acute attacks of hereditary angioedema	CMIC Holdings Co., Ltd.	—	—	—	—	—	Ecallantide (recombinant)			
2012	2012/8/16	(24yaku) No. 279	3	Lenvatinib mesylate	Thyroid cancer	Eisai Co., Ltd.	Unresectable thyroid cancer	Eisai Co., Ltd.	2015/3/26	Lenvima® Capsule 4 mg, Lenvima® Capsule 10 mg	Lenvima&reg	Lenvatinib mesylate			Approved
2012	2012/8/16	(24yaku) No. 280		Alemtuzumab (recombinant)	Chronic lymphocytic leukemia	Sanofi-aventis K.K.	Relapsed or refractory chronic lymphocytic leukemia	Sanofi K.K.	2014/9/26	MabCampath 30 mg I.V. Infusion	MabCampath®	Alemtuzumab (recombinant)			Approved
2012	2012/8/16	(24yaku) No. 281		SBC-102	Lysosomal acid lipase deficiency	Synageva BioPharma Corp.	—	—	—	—	—	—			
2012	2012/9/13	(24yaku) No. 282		Rituximab (recombinant)	Refractory nephrotic syndrome	Zenyaku Kogyo Co., Ltd.	Complicated nephrotic syndrome (frequently relapsing and steroid-dependent)	Zenyaku Kogyo Co., Ltd.	2014/8/29	Rituxan injection 10 mg/mL	Rituxan® Injection	Rituximab (recombinant)			Approved
2012	2012/9/13	(24yaku) No. 283		Bevacizumab (recombinant)	Glioblastoma	Chugai Pharmaceutical Co., Ltd	—	—	—	—	—	Bevacizumab (recombinant)	Designation revoked (2013/05/13)	2013/5/13	Revoked
2012	2012/9/13	(24yaku) No. 284		Infliximab (recombinant)	Refractory Kawasaki disease	Mitsubishi Tanabe Pharma Corporation	—	—	—	—	—	Infliximab (recombinant)			
2012	2012/9/13	(24yaku) No. 285		Infliximab (recombinant)	Intestinal, neuro-, and vasculo Behcet syndrome	Mitsubishi Tanabe Pharma Corporation	—	—	—	—	—	Infliximab (recombinant)			
2012	2012/9/13	(24yaku) No. 286	2	Sirolimus	Lymphangioleiomyomatosis (LAM)	Nobelpharma Co., Ltd.	Lymphangioleiomyomatosis	Nobelpharma Co., Ltd.	2014/7/4	Rapa l imus tablets 1mg	Rapa l imus® tablets 1mg	Sirolimus			Approved
2012	2012/9/13	(24yaku) No. 287		Vemurafenib	*BRAF*^{V600} mutation-positive malignant melanoma	Chugai Pharmaceutical Co., Ltd	*BRAF*mutation-positive malignant melanoma	Chugai Pharmaceutical Co., Ltd	2014/12/26	Zelboraf tablet 240 mg	Zelboraf®	Vemurafenib			Approved
2012	2012/9/13	(24yaku) No. 288		Tacrolimus hydrate	Interstitial pneumonia associated with polymyositis or dermatomyositis	Astellas Pharma Inc.	Interstitial pneumonia associated with polymyositis or dermatomyositis	Astellas Pharma Inc.	2013/6/14	Prograf capsule 0.5 mg Prograf capsule 1 mg	Prograf® Capsules 0.5mg Prograf® Capsules 1mg	Tacrolimus Hydrate			Approved
2012	2012/9/13	(24yaku) No. 289		Cell culture-derived whole virion prototype vaccine	Prophylaxis for pandemic influenza	Baxter Takeda Pharmaceutical Co., Ltd.	Prophylaxis for pandemic influenza	Baxter Takeda Pharmaceutical Co., Ltd.	2013/4/26	Cell culture influenza vaccine (prototype vaccine) "Baxter" Cell culture influenza vaccine (prototype vaccine) "Takeda" 5 mL	—	Cell culture influenza vaccine (prototype vaccine)			Approved
2012	2012/11/14	(24yaku) No. 290		Elvitegravir	HIV infection	Japan Tobacco, Inc.	HIV-1 infection	Japan Tobacco, Inc.	2013/3/25	Stribild combination tablet *HC2901	Stribild® Combination Tab.	Elvitegravir			Approved
2012	2012/11/14	(24yaku) No. 291		Cobicistat	Pharmacokinetic enhancement of anti-HIV agents	Japan Tobacco, Inc.	HIV-1 infection	Japan Tobacco, Inc.	2013/3/25	Stribild combination tablet *HC2911	Stribild® Combination Tab.	Cobicistat			Approved
2012	2012/11/14	(24yaku) No. 292	2	Dried polyethylene glycol-treated human immunoglobulin	Stevens-Johnson syndrome and toxic epidermal necrolysis (for which systemic steroid treatment is not sufficiently effective)	Nihon Pharmaceutical Co., Ltd.	Stevens-Johnson syndrome and toxic epidermal necrolysis (for which systemic steroid treatment is not sufficiently effective)	Nihon Pharmaceutical Co., Ltd.	2014/7/4	Kenketu glovenin-I for IV injection 500 mg Kenketu glovenin-I for IV injection 2500 mg Kenketu glovenin-I for IV injection 5000 mg	kenketu glovenin®—I for IV injection 500mg kenketu glovenin®—I for IV injection 2500mg kenketu glovenin®—I for IV injection 5000mg	Freeze-dried Polyethylene Glycol-treated Normal Human Immunoglobulin			Approved
2012	2012/11/14	(24yaku) No. 293		SAR302503	Myelofibrosis	Sanofi K.K.	—	—	—	—	—	—	Designation revoked (2015/05/25)	2015/5/25	Revoked
2012	2012/12/11	(24yaku) No. 294		Cinacalcet hydrochloride	Hypercalcemia associated with parathyroid carcinoma or intractable primary hyperparathyroidism	Kyowa Hakko Kirin Co., Ltd.	Hypercalcemia associated with parathyroid carcinoma or unresectable/postoperative recurrence primary hyperparathyroidism	Kyowa Hakko Kirin Co., Ltd.	2014/2/21	Regpara Tablet 25mg Regpara Tablet 75mg	REGPARA® TABLETS 25mg REGPARA® TABLETS 75mg	Cinacalcet Hydrochloride			Approved
2012	2012/12/11	(24yaku) No. 295		BMN110	Mucopolysaccharidosis Type IV A	BioMarin Pharmaceutical Inc.	Mucopolysaccharidosis Type IV A	BioMarin Pharmaceutical Inc.	2014/12/26	Vimizim I.V. Infusion 5mg	Vimizim®	Elosulfase Alfa (Genetical Recombination)			Approved
2012	2012/12/11	(24yaku) No. 296	1	Precipitated influenza vaccine cell culture (H5N1 strain)	Prophylaxis of H5N1 influenza	Kitasato Daiichi Sankyo Vaccine Co., Ltd.	Prophylaxis of H5N1 influenza	Kitasato Daiichi Sankyo Vaccine Co., Ltd.	2014/3/24	—	—	Precipitated influenza vaccine cell culture (H5N1 strain)			Approved
2012	2012/12/11	(24yaku) No. 297	2	Precipitated influenza vaccine cell culture (prototype vaccine)	Prophylaxis for new strains of influenza	Kitasato Daiichi Sankyo Vaccine Co., Ltd.	—	—	—	—	—	—			

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2012	2013/3/15	(25yaku) No. 298	1	Mogamulizumab (recombinant)	Peripheral T-cell lymphoma, cutaneous T-cell lymphoma	Kyowa Hakko Kirin Co., Ltd.	Relapsed or refractory CCR4-positive peripheral T-cell lymphoma, Relapsed or refractory CCR4-positive cutaneous T-cell lymphoma	Kyowa Hakko Kirin Co., Ltd.	2014/3/17	Poteligeo for IV infusion 20 mg	POTELIGEO® Injection	Mogamulizumab(recombinant)			Approved
2012	2013/3/15	(25yaku) No. 299	2	Bexarotene	Cutaneous T-cell lymphoma	Minophagen Pharmaceutical Co., Ltd.	—	—	—	—	—	—			
2012	2013/3/15	(25yaku) No. 300		Ipilimumab	Malignant melanoma	Bristol-Myers	—	—	—	—	—	—			
2013	2013/5/13	(25yaku) No. 301	1	Aminolevulinic acid hydrochloride	Visualization of tumor tissue during surgical resection of non-muscle invasive bladder cancer	Nobelpharma Co., Ltd. SBI Pharmaceuticals Co., Ltd.	—	—	—	—	—	Aminolevulinic acid hydrochloride			
2013	2013/5/13	(25yaku) No. 302		Rifaximin	Hepatic encephalopathy	ASKA Pharmaceutical. Co., Ltd.	—	—	—	—	—	—			
2013	2013/5/13	(25yaku) No. 303	2	Ozanezumab	Amyotrophic lateral sclerosis (ALS)	GlaxoSmithKline K.K.	—	—	—	—	—	—			
2013	2013/5/13	(25yaku) No. 304		Bevacizumab (recombinant)	Malignant glioma	Chugai Pharmaceutical Co., Ltd.	Malignant glioma	Chugai Pharmaceutical Co., Ltd.	2013/6/14	Avastin for IV infusion 100 mg/4 mL Avastin for IV infusion 400 mg/16 mL	AVASTIN® 100mg/4mL Intravenous Infusion AVASTIN® 400mg/16mL Intravenous Infusion	Bevacizumab (recombinant) (JAN)			Approved
2013	2013/6/17	(25yaku) No. 305	2	Dried sulfonated human immunoglobulin	Optic neuritis (for which steroid treatment is not sufficiently effective)	Kaketsuken, Teijin Pharma Limited	—	—	—	—	—	Freeze-dried Sulfonated Normal Human Immunoglobulin			
2013	2013/6/17	(25yaku) No. 306		Denosumab (Genetical Recombinationt)	Giant cell tumor of bone	Daiichi Sankyo Company, Limited	Giant cell tumor of bone	Daiichi Sankyo Company, Limited	2014/5/23	RANMARK SUBCUTANEOUS INJECTION 120mg	RANMARK® SUBCUTANEOUS INJECTION	Denosumab (Genetical Recombinationt)			Approved
2013	2013/6/17	(25yaku) No. 307	1	Ambrisentan	Chronic thromboembolic pulmonary hypertension	GlaxoSmithKline K.K.	—	—	—	—	—	Ambrisentan			
2013	2013/6/17	(25yaku) No. 308	1、1	ONO-4538	Malignant melanoma	Ono Pharmaceutical Co., Ltd.	Unresectable Melanoma	Ono Pharmaceutical Co., Ltd.	2014/7/4	OPDIVO Intravenous Infusion 20mg OPDIVO Intravenous Infusion 100mg	OPDIVO® Intravenous Infusion	Nivolumab(Genetical Recombination)			Approved
2013	2013/8/12	(25yaku) No. 309		Talaporfin sodium	Malignant brain tumors	Meiji Seika Pharma Co., Ltd.	Primary malignant brain tumor limited to cases treated with surgical resection	Meiji Seika Pharma Co., Ltd.	2013/9/20	Laserphyrin for injection 100 mg	LASERPHYRIN® FOR INJECTION	Talaporfin Sodium	Designation was transferred from (20yaku) No. 219 with the change in indication from malignant glioma to malignant brain tumor (expansion of range).		Approved

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2013	2013/9/3	(25yaku) No. 310		Lomitapide mesylate	Homozygous familial hypercholesterolemia (HoFH)	Aegerion Pharmaceuticals, Inc.	—	—	—	—	—	—			
2013	2013/9/3	(25yaku) No. 311		Rituximab (recombinant)	Chronic idiopathic thrombocytopenic purpura	Zenyaku Kogyo Co., Ltd.	—	—	—	—	—	Rituximab (recombinant)			
2013	2013/9/3	(25yaku) No. 312		BYM338	Inclusion body myositis	Novartis Pharma K.K.	—	—	—	—	—	—			
2013	2013/9/13	(25yaku) No. 313	1	Mepolizumab	Churg-Strauss syndrome	GlaxoSmithKline K.K.	—	—	—	—	—	—			
2013	2013/9/13	(25yaku) No. 314		Dolutegravir sodium	HIV infection	ViiV Healthcare K.K.	HIV infection	ViiV Healthcare K.K.	2014/3/24	Tivicay tablet 50mg Triumeq combination tablet ※HC3141	Tivicay®Tablets Triumeq® Combination Tables	dolutegravir sodium			Approved
2013	2013/9/13	(25yaku) No. 315		Sorafenib tosylate	Thyroid cancer	Bayer Holding Ltd.	Unresectable differentiated thyroid cancer	Bayer Holding Ltd.	2014/6/20	Nexavar tablets 200mg	Nexavar®200mg	Sorafenib tosylate			Approved
2013	2013/9/13	(25yaku) No. 316		Alectinib hydrochloride	Unresectable progressive or recurrent *ALK* fusion gene-positive non-small cell lung cancer	Chugai Pharmaceutical Co., Ltd	Unresectable progressive or recurrent *ALK* fusion gene-positive non-small cell lung cancer	Chugai Pharmaceutical Co., Ltd	2014/7/4	Alecensa capsule 20 mg Alecensa capsule 40 mg	Alecensa®	Alectinib Hydrochloride			Approved
2013	2013/09/13 2015/04/22 *	(25yaku) No. 317		Trametinib	*BRAF*^{V600} mutation-positive malignant melanoma	GlaxoSmithKline K.K.,2013-9-13 Novartis Pharma K.K., 2015-04-22 *	—	—	—	—	—	—			
2013	2013/09/13 2015/04/22 *	(25yaku) No. 318		Dabrafenib	*BRAF*^{V600} mutation-positive malignant melanoma	GlaxoSmithKline K.K.,2013-9-13 Novartis Pharma K.K., 2015-04-22 *	—	—	—	—	—	—			
2013	2013/11/15	(25yaku) No. 319		Propranolol hydrochloride	Infantile hemangiomas	Maruho Co., Ltd.	—	—	—	—	—	Propranolol Hydrochloride			
2013	2013/12/4	(25yaku) No. 320		Human C1 inhibitor	Prevention and treatment of angioedema episodes in patients with human C1 inhibitor (C1 INH) deficiency due to heredity or spontaneous mutations	ViroPharma Incorporated	—	—	—	—	—	—			
2013	2013/12/4	(25yaku) No. 321		Vandetanib	Thyroid cancer	AstraZeneca K.K.	—	—	—	—	—	Vandetanib			
2013	2013/12/4	(25yaku) No. 322		MEK162	*NRAS* or *BRAF*^{V600} mutation-positive malignant melanoma	Novartis Pharma K.K.	—	—	—	—	—	—			
2013	2013/12/4	(25yaku) No. 323		LGX818	*BRAF*^{V600} mutation-positive malignant melanoma	Novartis Pharma K.K.	—	—	—	—	—	—			
2013	2013/12/4	(25yaku) No. 324		Bosutinib hydrate	Chronic myelogenous leukemia with resistance or intolerance to previous treatments	Pfizer Japan Inc.	Chronic myelogenous leukemia with resistance or intolerance to previous treatments	Pfizer Japan Inc.	2014/9/26	Boslif tablet 100 mg	BOSLIF®	Bosutinib Hydrate			Approved
2013	2013/12/12	(25yaku) No. 325		NPR-01	External fistulas due to Crohn's disease (including anal fistulas)	Nihon Pharmaceutical Co., Ltd.	—	—	—	—	—	—			
2013	2013/12/12	(25yaku) No. 326		JR-031	Acute graft-versus-host disease	Japan Chemical Research Co., Ltd.	—	—	—	—	—	—			
2013	2013/12/12	(25yaku) No. 327	2	Modafinil	Excessive daytime sleepiness associated with idiopathic hypersomnia	Alfresa Pharma Corporation	—	—	—	—	—	Modafinil			
2013	2014/2/26	(26yaku) No. 328	1	Dried sulfonated human immunoglobulin	Improvement of microscopic polyangiitis (limited to cases in which steroids are inadequate)	Kaketsuken, Teijin Pharma Limited	—	—	—	—	—	Freeze-dried Sulfonated Normal Human Immunoglobulin			
2013	2014/2/26	(26yaku) No. 329	1	Pralatrexate	Peripheral T-cell lymphoma, cutaneous T-cell lymphoma	Mundipharma K.K.	—	—	—	—	—				
2013	2014/3/17	(26yaku) No. 330		Talaporfin Sodium	Local failure after chemoradiotherapy or radiotherapy for esophageal cancer	Meiji Seika Pharma Co., Ltd.	Local failure after chemoradiotherapy or radiotherapy for esophageal cancer	Meiji Seika Pharma Co., Ltd.	2015/5/26	Leserphyrin for injection 100 mg	LASERPHYRIN® FOR INJECTION	Talaporfin Sodium			Approved

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2013	2014/3/17	(26yaku) No. 331		Darbepoetin Alfa (Genetical Recombination)	Anemia with Myelodysplastic Syndromes	Kyowa Hakko Kirin Co., Ltd.	Anemia with Myelodysplastic Syndromes	Kyowa Hakko Kirin Co., Ltd.	2014/12/18	Nesp Injection Plastic 5μg Syringe Nesp Injection Plastic 10μgSyringe Nesp Injection Plastic 15μgSyringe Nesp Injection Plastic 20μgSyringe Nesp Injection Plastic 30μgSyringe Nesp Injection Plastic 40μgSyringe Nesp Injection Plastic 60μgSyringe Nesp Injection Plastic120μgSyringe Nesp Injection Plastic180μgSyringe	NESP® INJECTION PLASTIC SYRINGE	Darbepoetin Alfa (Genetical Recombination)			Approved
2014	2014/5/13	(26yaku) No. 332		EPI-743	Leigh syndrome	Dainippon Sumitomo Pharma Co., Ltd.	—	—	—	—	—				
2014	2014/5/13	(26yaku) No. 333		catridecacog	Inhibition of bleeding in patients with congenital factor XIII A-subunit deficiency	Novo Nordisk Pharma Ltd.	Inhibition of bleeding tendency in patients with congenital factor XIII A-subunit deficiency	Novo Nordisk Pharma Ltd.	2015/3/26	Novo thirteen 2500	Novo Thirteen®	Catridecacog (Genetical Recombination)			Approved
2014	2014/5/13	(26yaku) No. 334		Canakinumab (Genetical Recombination)	Mevalonate Kinase. Deficiency	Novartis Pharma K.K.	—	—	—	—	—	Canakinumab (Genetical Recombination)			
2014	2014/5/13	(26yaku) No. 335		Canakinumab (Genetical Recombination)	TNF receptor-associated periodic syndrome	Novartis Pharma K.K.	—	—	—	—	—	Canakinumab (Genetical Recombination)			
2014	2014/5/13	(26yaku) No. 336		Canakinumab (Genetical Recombination)	Familial Mediterranean fever	Novartis Pharma K.K.	—	—	—	—	—	Canakinumab (Genetical Recombination)			
2014	2014/5/13	(26yaku) No. 337	4	MC710 (freeze dried human blood coagulation factor X added to activated blood coagulation factor VII)	Control of hemorrhage in patients with inhibitors against blood coagulation FVIII and FIX	Kaketsuken	Control of hemorrhage in patients with inhibitors against blood coagulation FVIII and FIX	Kaketsuken	2014/7/4	Byclot	Byclot®	freeze dried human blood coagulation factor X added to activated blood coagulation factor VII			Approved
2014	2014/6/11	(26yaku) No. 338		icatibant	Acute attacks of hereditary angioedema	Shire Japan KK	—	—	—	—	—	—			
2014	2014/6/11	(26yaku) No. 339		ibrutinib	Chronic lymphocytic leukemia small lymphocytic lymphoma Mantle cell lymphoma	Janssen Pharmaceutical K.K.	—	—	—	—	—	—			
2014	2014/6/11	(26yaku) No. 340		Tocilizumab (genetical recombination)	Large Vessel Vasculitis	Chugai Pharmaceutical Co., Ltd	—	—	—	—	—	Tocilizumab (genetical recombination)			
2014	2014/6/11	(26yaku) No. 341		Eribulin mesilate	Malignant soft tissue tumors	Eisai Co., Ltd.	—	—	—	—	—	Eribulin mesilate			
2014	2014/6/11	(26yaku) No. 342		Pomalidomide	Relapsed or refractory multiple myeloma	Celgene K.K.	Relapsed or refractory multiple myeloma	Celgene K.K.	2015/3/26	Pomalyst capsule1mg Pomalyst capsule2mg Pomalyst capsule3mg Pomalyst capsule4mg	Pomalyst® Capsules	Pomalidomide			Approved
2014	2014/8/21	(26yaku) No. 343		Rituximab (recombinant)	Acquired thrombotic thrombocytopenic purpura	Zenyaku Kogyo Co., Ltd.	—	—	—	—	—	Rituximab (recombinant)			
2014	2014/8/21	(26yaku) No. 344		ISIS 420915	Transthyretin Familial Amyloid Polyneuropathy	GlaxoSmithKline K.K.	—	—	—	—	—	—			
2014	2014/8/21	(26yaku) No. 345		BG00012	Prevention of relapse and delay of physical disability progression in multiple sclerosis	Biogen Idec Japan Ltd.	—	—	—	—	—	—			

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2014	2014/8/21	(26yaku) No. 346		asfotase alfa	Hypophosphatasia	Alexion Pharma Godo Kaisha	—	—	—	—	—	—			
2014	2014/9/17	(26yaku) No. 347		Selexipag	Pulmonary arterial hypertension	Nippon Shinyaku Co., Ltd	—	—	—	—	—	Selexipag			
2014	2014/9/17	(26yaku) No. 348		Vigabatrin	Epilepsia nutans	Sanofi K.K.	—	—	—	—	—	Vigabatrin			
2014	2014/9/17	(26yaku) No. 349		Panobinostat Lactate	Relapsed or refractory multiple myeloma	Novartis Pharma K.K.	—	—	—	—	—	Panobinostat Lactate			
2014	2014/9/17	(26yaku) No. 350		MK-3475	Malignant melanoma	MSD K.K.	—	—	—	—	—	—			
2014	2014/9/17	(26yaku) No. 351		Peginterferon alfa-2b (generical recombination)	Adjuvant chemotherapy for malignant melanoma	MSD K.K.	Adjuvant chemotherapy for malignant melanoma	MSD K.K.	2015/5/26	Pegintron powder for SC injection 50μg／0.5mL Pegintron powder for SC injection 100μg／0.5mL Pegintron powder for SC injection 150μg／0.5mL	PEGINTRON® Powder for Injection	Peginterferon alfa-2b (generical recombination)			Approved
2014	2014/11/20	(26yaku) No. 352		Thalidomide	Crow-Fukase (POEMS) syndrome	Fujimoto Pharmaceutical Corporation	—	—	—	—	—	Thalidomide			
2014	2014/11/20	(26yaku) No. 353		Eculizumab(genetical recombination)	Prevention of NMO-IgG-positive relapsing neuromyelitis optica (NMO)	Alexion Pharma Godo Kaisha	—	—	—	—	—	Eculizumab(genetical recombination)			
2014	2014/11/20	(26yaku) No. 354		Isopropyl unoprostone	Retinitis pigmentosa	R-Tech Ueno, Ltd.	—	—	—	—	—	Isopropyl unoprostone			
2014	2014/11/20	(26yaku) No. 355		Nitric Oxide	Treatment of pre-,peri- and post- operative pulmonary hypertension in adults and children (including newborns) in heart surgery in order to selectively decrease pulmonary arterial pressure and improve right ventricular function and oxygenation	Ino Therapeutics, LLC	—	—	—	—	—	Nitric Oxide			
2014	2014/11/20	(26yaku) No. 356		teduglutide(genetical	Short Bowel Syndrome	NPS Pharma K.K. and G.K	—	—	—	—	—	—			
2014	2014/11/20	(26yaku) No. 357		carglumic acid	Inhibition of rising blood levels of ammonia in the following associated diseases: N-acetylglutamate synthetase deficienc,Isovaleric academia,Methylmalonic academia and Propionic Acidemia	Pola Pharma INC.	—	—	—	—	—	—			

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2014	2014/12/8	(26yaku) No. 358		Eculizumab(genetical	Intractable myasthenia gravis	Alexion Pharma Godo Kaisha	—	—	—	—	—	Eculizumab(genetical recombination)			
2014	2014/12/8	(26yaku) No. 359		Bosentan hydrate	Digital ulcers of systemic sclerosis	Actelion Pharmaceuticals Japan Ltd.	—	—	—	—	—	Bosentan hydrate			
2015	2015/5/25	(27yaku) No. 360		metirosine	Improvement of catecholamine excess and various symptoms in pheochromocytoma	Ono Pharmaceutical Co., Ltd.	—	—	—	—	—	—			
2015	2015/5/25	(27yaku) No. 361		Rituximab (genetical recombination)	Inhibition of antibody-mediated rejection in the following ABO-incompatible transplantation ：kidney transplantation ,liver transplantation	Zenyaku Kogyo Co., Ltd.	—	—	—	—	—	Rituximab (genetical recombination)			