◆PMDA Approved Biosimilars (as of Oct 2026)

Approval Date	No.	Original Biopharmaceutical	Brand Name (Company)	Active Ingredient	Indications at Initial Approval	Type
September 16, 2026	49	Stelara	(1) Ustekinumab BS 45 mg Syringe for S.C. Injection "Meiji" (2) Ustekinumab BS for I.V. Infusion130 mg "Meiji" (Meiji Seika Pharma Co., Ltd.)	Ustekinumab (Genetical Recombination) [Ustekinumab Biosimilar 5]	(1) ・Treatment of the following disease in patients who have not sufficiently responded to conventional therapies: plaque psoriasis and psoriatic arthritis ・The maintenance therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments) ・the maintenance therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments) (2) ・The induction therapy for moderate to severe active Crohn's disease (for use only in patients who have not sufficiently responded to conventional treatments) ・The remission induction therapy of moderate to severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments)	Monoclonal antibody
August 24, 2026	48	G-Lasta	Pegfilgrastim BS Subcutaneous Injection 3.6 mg "GRP" (Global Regulatory Partners GK)	Pegfilgrastim (Genetical Recombination) [Pegfilgrastim Biosimilar 2]	Prevention of febrile neutropenia in patients receiving cancer chemotherapy	Cytokine
March 23, 2026	47	Xolair	Omalizumab BS 75 mg Syringes for S.C. Injection "CT" Omalizumab BS 150 mg Syringes for S.C. Injection "CT" Omalizumab BS 75 mg Pens for S.C. Injection "CT" Omalizumab BS 150 mg Pens for S.C. Injection "CT" (Celltrion Healthcare Japan K.K.)	Omalizumab (Genetical Recombination) [Omalizumab Biosimilar 1]	Treatment of bronchial asthma (for use only in patients with intractable bronchial asthma whose asthmatic responses are uncontrollable with conventional therapies) Treatment of seasonal allergic rhinitis (for use only in severe or the most severe patients who have not responded sufficiently to conventional therapies) Treatment of chronic idiopathic urticaria (for use only in patients who have not responded sufficiently to conventional therapies)	Monoclonal antibody
March 23, 2026	46	Actemra	(1)Tocilizumab BS for Intravenous Infusion 80 mg "MA" (2)Tocilizumab BS for Intravenous Infusion 200 mg "MA" (3)Tocilizumab BS for Intravenous Infusion 400 mg "MA" (4)Tocilizumab BS 162 mg Syringes for S.C. Injection "MA" (5)Tocilizumab BS 162 mg Auto-Injectors for S.C. Injection "MA" (Mochida Pharmaceutical Co., Ltd.)	Tocilizumab (Genetical Recombination) [Tocilizumab Biosimilar 2]	(1) (2) (3) ・Treatment of rheumatoid arthritis (including the prevention of structural joint damage), polyarticular-course juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis, in patients who have not sufficiently responded to conventional treatments ・Improvement of various symptoms and laboratory findings associated with Castleman's disease for whom resection of lymph nodes is not indicated ・Treatment of cytokine release syndrome induced by the treatment of malignant tumor ・Treatment of pneumonia caused by SARS-CoV-2 (only for the patients requiring supplemental oxygen) (4) (5) Treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments	Monoclonal antibody
March 23, 2026	45	Eylea	Aflibercept BS Solution for Intravitreal Injection 40 mg/mL "CT" Aflibercept BS Solution Kit for Intravitreal Injection 40 mg/mL "CT" (Celltrion Healthcare Japan K.K.)	Aflibercept (Genetical Recombination) [Aflibercept Biosimilar 4]	Treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization, macular edema following retinal vein occlusion, choroidal neovascularization in patients with pathologic myopia, and diabetic macular edema	Fusion protein

December 22, 2025	44	Stelara	Ustekinumab BS 45 mg Syringe for S.C. Injection “Nipro” Ustekinumab BS for I.V. Infusion130 mg “Nipro” * (Nipro Corporation) *Approved in 2026	Ustekinumab (Genetical Recombination) [Ustekinumab Biosimilar 4]	Treatment of the following disease in patients who have not sufficiently responded to conventional therapies: plaque psoriasis and psoriatic arthritis	Monoclonal antibody
September 19, 2025	43	Simponi	Golimumab BS 50 mg Syringe for S.C. Injection “F” (Fuji Pharma Co., Ltd.)	Golimumab（Genetical Recombination）[Golimumab Biosimilar 1]	Treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments	Monoclonal antibody
September 19, 2025	42	Actemra	(1)Tocilizumab BS for Intravenous Infusion 80 mg “CT” (2)Tocilizumab BS for Intravenous Infusion 200 mg “CT” (3)Tocilizumab BS for Intravenous Infusion 400 mg “CT” (4)Tocilizumab BS 162 mg Syringes for S.C. Injection “CT” (5)Tocilizumab BS 162 mg Auto-Injector for S.C. Injection “CT” (Celltrion Healthcare Japan K.K.)	Tocilizumab（Genetical Recombination）[Tocilizumab Biosimilar 1]	(1) (2) (3) ・Treatment of rheumatoid arthritis (including the prevention of structural joint damage), polyarticular-course juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis, in patients who have not sufficiently responded to conventional treatments ・Improvement of various symptoms and laboratory findings associated with Castleman’s disease for whom resection of lymph nodes is not indicated ・Treatment of cytokine release syndrome induced by the treatment of malignant tumor (4) (5) Treatment of rheumatoid arthritis (including the prevention of structural joint damage) in patients who have not sufficiently responded to conventional treatments	Monoclonal antibody
September 19, 2025	41	Ranmark	Denosumab BS 120 mg RM for S.C. Injection “F” (Fuji Pharma Co., Ltd.)	Denosumab（Genetical Recombination）[Denosumab Biosimilar 1]	Treatment of bone lesions due to multiple myeloma and bone metastasis of solid tumor	Monoclonal antibody
September 19, 2025	40	Eylea	Aflibercept BS Solution for Intravitreal Injection 40 mg/mL “SCD” Aflibercept BS Kit for Intravitreal Injection 40 mg/mL “SCD” (SamChunDang Pharm. Co., Ltd.)	Aflibercept（Genetical Recombination）[Aflibercept Biosimilar 3]	Treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization, macular edema following retinal vein occlusion, and choroidal neovascularization in patients with pathologic myopia	Fusion protein
September 19, 2025	39	Eylea	Aflibercept BS Solution 40 mg/mL for IVT Injection “NIT” Aflibercept BS Kit 40 mg/mL for IVT Injection “NIT” (Fuji Pharma Co., Ltd.)	Aflibercept（Genetical Recombination）[Aflibercept Biosimilar 2]	Treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization, macular edema following retinal vein occlusion, and choroidal neovascularization in patients with pathologic myopia	Fusion protein
March 27, 2025	38	Stelara	Ustekinumab BS 45 mg Syringe for S.C. Injection “CT” Ustekinumab BS for I.V. Infusion 130 mg “CT” * (Celltrion Healthcare Japan K.K.) *Approved in 2026	Ustekinumab (Genetical Recombination) [Ustekinumab Biosimilar 3]	Treatment of the following disease in patients who have not sufficiently responded to conventional therapies: plaque psoriasis and psoriatic arthritis	Monoclonal antibody
December 27, 2024	37	Stelara	Ustekinumab BS 45 mg Syringe for S.C. Injection “YD” Ustekinumab BS for I.V. Infusion130 mg “YD” * (Yoshindo Holdings Inc.) *Approved in 2026	Ustekinumab (Genetical Recombination) [Ustekinumab Biosimilar 2]	Treatment of the following disease in patients who have not sufficiently responded to conventional therapies: plaque psoriasis and psoriatic arthritis	Monoclonal antibody
June 24, 2024	36	Eylea	Aflibercept BS Solution for Intravitreal Injection 40 mg/mL “GRP” (Global Regulatory Partners GK)	Aflibercept（Genetical Recombination） [Aflibercept Biosimilar 1]	Treatment of macular edema following retinal vein occlusion, choroidal neovascularization in patients with pathologic myopia, and diabetic macular edema.	Fusion protein

September 25, 2023	35	Humira	Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.2 mL “CTNK” Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.4 mL “CTNK” Adalimumab BS Subcutaneous Injection 80 mg Syringe 0.8 mL “CTNK” Adalimumab BS Subcutaneous Injection 40 mg Pen 0.4 mL “CTNK” Adalimumab BS Subcutaneous Injection 80 mg Pen 0.8 mL “CTNK” (Nippon Kayaku Co., Ltd.)	Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 4]	Treatment of rheumatoid arthritis (including the prevention of structural joint damage), and the treatment of the following diseases in patients who have not sufficiently responded to conventional treatments: polyarticular-course juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis, intestinal Behcet’ s disease, non-infectious intermediate uveitis, posterior uveitis, and panuveitis; the remission induction therapy and maintenance therapy for moderate to severe active Crohn’s disease (for use only in patients who have not sufficiently responded to conventional therapies), and the treatment of moderate or severe ulcerative colitis (for use only in patients who have not sufficiently responded to conventional treatments)	Monoclonal antibody
September 25, 2023	34	Stelara	Ustekinumab BS 45 mg Syringe for S.C. Injection “F” Ustekinumab BS 90 mg Syringe for S.C. Injection “F” * (Fuji Pharma Co., Ltd.) *Approved in 2026	Ustekinumab (Genetical Recombination) [Ustekinumab Biosimilar 1]	Treatment of the following disease in patients who have not sufficiently responded to conventional therapies: plaque psoriasis and psoriatic arthritis	Monoclonal antibody
September 25, 2023	33	G-Lasta	Pegfilgrastim BS Subcutaneous Injection 3.6 mg “Mochida” (Mochida Pharmaceutical Co., Ltd.) Pegfilgrastim BS Subcutaneous Injection 3.6 mg “Nipro” (Mochida Pharmaceutical Sales Co., Ltd.)	Pegfilgrastim (Genetical Recombination) [Pegfilgrastim Biosimilar 1]	Prevention of febrile neutropenia in patients receiving cancer chemotherapy	Cytokine
September 26, 2022	32	Avastin	Bevacizumab BS for Intravenous Infusion 100 mg “CTNK” Bevacizumab BS for Intravenous Infusion 400 mg “CTNK” (Nippon Kayaku Co., Ltd.)	Bevacizumab (Genetical Recombination) [Bevacizumab Biosimilar 4]	Treatment of unresectable advanced or recurrent colon or rectal cancer, unresectable advanced or recurrent non-squamous non-small cell lung cancer, and unresectable or recurrent breast cancer	Monoclonal antibody
January 20, 2022	31	Avastin	Bevacizumab BS Intravenous Infusion 100 mg “Nichi-Iko” Bevacizumab BS Intravenous Infusion 400 mg “Nichi-Iko” (Nichi-Iko Pharmaceutical Co., Ltd.)	Bevacizumab (Genetical Recombination) [Bevacizumab Biosimilar 3]	Treatment of unresectable advanced or recurrent colon or rectal cancer and unresectable advanced or recurrent non-squamous non-small cell lung cancer	Monoclonal antibody
September 27, 2021	30	Lucentis	Ranibizumab BS Intravitreal Injection kit 10 mg/mL “Senju” (Senju Pharmaceutical Co., Ltd.)	Ranibizumab (Genetical Recombination) [Ranibizumab Biosimilar 1]	Treatment of age-related macular degeneration associated with subfoveal choroidal neovascularization or choroidal neovascularization in patients with pathologic myopia	Monoclonal antibody
March 23, 2021	29	Humira	Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.2 mL “MA” Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.4 mL “MA” Adalimumab BS Subcutaneous Injection 80 mg Syringe 0.8 mL “MA” Adalimumab BS Subcutaneous Injection 40 mg Pen 0.4 mL “MA” (Mochida Pharmaceutical Co., Ltd.)	Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 3]	Treatment of rheumatoid arthritis (including the prevention of structural joint damage), and the treatment of the following diseases in patients who have not responded sufficiently to conventional treatments: polyarticular-course juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis and intestinal Beh ç et’s disease; the remission induction therapy and maintenance therapy for moderate to severe active Crohn’s disease, and treatment of moderate to severe ulcerative colitis	Monoclonal antibody
March 23, 2021	28	NovoRapid	Insulin Aspart BS Injection SoloStar NR “Sanofi” Insulin Aspart BS Injection Cart NR “Sanofi” Insulin Aspart BS Injection 100 I.U./mL NR “Sanofi” (Sanofi K.K.)	Insulin aspart (Genetical Recombination) [Insulin Aspart Biosimilar 1]	Treatment of diabetes mellitus in cases where insulin therapy is indicated	Hormone
January 22, 2021	27	Humira	Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.4 mL “Daiichi Sankyo” Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.8 mL “Daiichi Sankyo” Adalimumab BS Subcutaneous Injection 40 mg Pen 0.8 mL “Daiichi Sankyo” (Daiichi Sankyo Co., Ltd.)	Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 2]	Treatment of rheumatoid arthritis (including the prevention of structural joint damage), and the treatment of the following diseases in patients who have not responded sufficiently to conventional treatments: plaque psoriasis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis, polyarticular-course juvenile idiopathic arthritis, and intestinal Behcet’s disease	Monoclonal antibody

June 29, 2020	26	Humira	Adalimumab BS Subcutaneous Injection 20 mg Syringe 0.4 mL “FKB” Adalimumab BS Subcutaneous Injection 40 mg Syringe 0.8 mL “FKB” Adalimumab BS Subcutaneous Injection 40 mg Pen 0.8 mL “FKB” (Fujifilm Kyowa Kirin Biologics Co., Ltd.)	Adalimumab (Genetical Recombination) [Adalimumab Biosimilar 1]	Treatment of rheumatoid arthritis (including the prevention of structural joint damage), and the treatment of the following diseases in patients who have not responded sufficiently to conventional treatments: polyarticular course juvenile idiopathic arthritis, plaque psoriasis, psoriatic arthritis, pustular psoriasis, ankylosing spondylitis and intestinal Behcet’ s disease; and the remission induction therapy and maintenance therapy for moderate to severe active Crohn’s disease (for use only in patients who have not sufficiently responded to conventional therapies)	Monoclonal antibody
March 25, 2020	25	Humalog	Insulin Lispro BS Injection HU Solostar “Sanofi” Insulin Lispro BS Injection HU Cart “Sanofi” Insulin Lispro BS Injection HU 100 U/mL “Sanofi” (Sanofi K.K.)	Insulin lispro (Genetical Recombination) [Insulin Lispro Biosimilar 1]	Treatment of diabetes mellitus in cases where insulin therapy is indicated	Hormone
September 20, 2019	24	Rituxan	Rituximab BS Intravenous Infusion 100 mg [Pfizer] Rituximab BS Intravenous Infusion 500 mg [Pfizer] (Pfizer Japan Inc.)	Rituximab (Genetical Recombination) [Rituximab Biosimilar 2]	Treatment of CD20-positive B-cell non-Hodgkin’s lymphoma, CD20-positive B-cell lymphoproliferative disorder associated with immunosuppression, granulomatosis with polyangiitis, and microscopic polyangiitis	Monoclonal antibody
September 20, 2019	23	Avastin	Bevacizumab BS Intravenous Drip Infusions 100 mg “Amgen” Bevacizumab BS Intravenous Drip Infusions 400 mg “Amgen” (Amgen K.K.)	Bevacizumab (Genetical Recombination) [Bevacizumab Biosimilar 2]	Treatment of unresectable advanced or recurrent colon or rectal cancer	Monoclonal antibody
September 20, 2019	22	Nesp	Darbepoetin Alfa BS Injection 5 μg Syringe “MYL” * Darbepoetin Alfa BS Injection 10 μg Syringe “MYL” * Darbepoetin Alfa BS Injection 15 μg Syringe “MYL” * Darbepoetin Alfa BS Injection 20 μg Syringe “MYL” * Darbepoetin Alfa BS Injection 30 μg Syringe “MYL” * Darbepoetin Alfa BS Injection 40 μg Syringe “MYL” * Darbepoetin Alfa BS Injection 60 μg Syringe “MYL” * Darbepoetin Alfa BS Injection 120 μg Syringe “MYL” * Darbepoetin Alfa BS Injection 180 μg Syringe “MYL” * *Discontinued from marketing	Darbepoetin alfa (Genetical Recombination) [Darbepoetin Alfa Biosimilar 3]	Treatment of nephrogenic anaemia	Erythropoiesis stimulating agent
September 20, 2019	21	Nesp	Darbepoetin Alfa BS 5 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 10 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 15 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 20 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 30 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 40 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 60 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 120 μg Syringe for Injection “Sanwa” Darbepoetin Alfa BS 180 μg Syringe for Injection “Sanwa” (Sanwa Kagaku Kenkyusho Co., Ltd.)	Darbepoetin alfa (Genetical Recombination) [Darbepoetin Alfa Biosimilar 2]	Treatment of nephrogenic anaemia	Erythropoiesis stimulating agent
September 20, 2019	20	Nesp	Darbepoetin Alfa BS Injection 5 μg Syringe [JCR] Darbepoetin Alfa BS Injection 10 μg Syringe [JCR] Darbepoetin Alfa BS Injection 15 μg Syringe [JCR] Darbepoetin Alfa BS Injection 20 μg Syringe [JCR] Darbepoetin Alfa BS Injection 30 μg Syringe [JCR] Darbepoetin Alfa BS Injection 40 μg Syringe [JCR] Darbepoetin Alfa BS Injection 60 μg Syringe [JCR] Darbepoetin Alfa BS Injection 120 μg Syringe [JCR] Darbepoetin Alfa BS Injection 180 μg Syringe [JCR] (JCR Pharmaceuticals Co., Ltd.)	Darbepoetin alfa (Genetical Recombination) [Darbepoetin Alfa Biosimilar 1]	Treatment of nephrogenic anaemia	Erythropoiesis stimulating agent
September 20, 2019	19	Forteo	Teriparatide BS Subcutaneous Injection Kit 600 μg “MOCHIDA” (Mochida Pharmaceutical Co., Ltd.)	Teriparatide (Genetical Recombination) [Teriparatide Biosimilar 1]	Treatment of osteoporosis with a high risk of fracture	Hormone

June 18, 2019	18	Avastin	Bevacizumab BS Intravenous Infusion 100 mg [Pfizer] Bevacizumab BS Intravenous Infusion 400 mg [Pfizer] (Pfizer Japan Inc.)	Bevacizumab (Genetical Recombination) [Bevacizumab Biosimilar 1]	Treatment of unresectable advanced or recurrent colorectal cancer	Monoclonal antibody
March 26, 2019	17	Enbrel	Etanercept BS 10 mg Syringe 1.0 mL for S.C. Inj. "TY" Etanercept BS 25 mg Syringe 0.5 mL for S.C. Inj. "TY" Etanercept BS 50 mg Syringe 1.0 mL for S.C. Inj. "TY" Etanercept BS 50 mg Pen 1.0 mL for S.C. Inj. "TY" (Yoshindo Holdings Inc.) Etanercept BS 10 mg Syringe 1.0 mL for S.C. Inj. "Nichiiko" Etanercept BS 25 mg Syringe 0.5 mL for S.C. Inj. "Nichiiko" Etanercept BS 50 mg Syringe 1.0 mL for S.C. Inj. "Nichiiko" Etanercept BS 50 mg Pen 1.0 mL for S.C. Inj. "Nichiiko" (Nichi-Iko Pharmaceutical Co., Ltd.)	Etanercept (Genetical Recombination) [Etanercept Biosimilar 2]	Treatment of rheumatoid arthritis (including the prevention of structural joint damage) and polyarticular-course juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional therapies	Fusion protein
September 21, 2018	16	Herceptin	Trastuzumab BS for Intravenous Infusion 60 mg [Pfizer] Trastuzumab BS for Intravenous Infusion 150 mg [Pfizer] (Pfizer Japan Inc.)	Trastuzumab (Genetical Recombination) [Trastuzumab Biosimilar 3]	Treatment of breast cancer overexpressing HER2 and unresectable advanced or recurrent gastric cancer overexpressing HER2	Monoclonal antibody
September 21, 2018	15	Herceptin	Trastuzumab BS for Intravenous Drip Infusions 60 mg "Daiichi Sankyo" * Trastuzumab BS for Intravenous Drip Infusions 150 mg "Daiichi Sankyo" * *Discontinued from marketing	Trastuzumab (Genetical Recombination) [Trastuzumab Biosimilar 2]	Treatment of breast cancer overexpressing HER2 and unresectable advanced or recurrent gastric cancer overexpressing HER2	Monoclonal antibody
September 21, 2018	14	Fabrazyme	Agalsidase Beta BS I.V. Infusion 5 mg [JCR] Agalsidase Beta BS I.V. Infusion 35 mg [JCR] (JCR Pharmaceuticals Co., Ltd.)	Agalsidase beta (Genetical Recombination) [Agalsidase Beta Biosimilar 1]	Treatment of Fabry disease	Enzyme
July 2, 2018	13	Remicade	Infliximab BS for I.V. Infusion 100 mg [Pfizer] (Pfizer Japan Inc.)	Infliximab (Genetical Recombination) [Infliximab Biosimilar 3]	Treatment of rheumatoid arthritis, psoriasis, Crohn's disease, and ulcerative colitis	Monoclonal antibody
March 23, 2018	12	Herceptin	Trastuzumab BS for I.V. Infusion 60 mg "NK" Trastuzumab BS for I.V. Infusion 150 mg "NK" (Celltrion Healthcare Japan K.K.) Trastuzumab BS for I.V. Infusion 60 mg "CTH" * Trastuzumab BS for I.V. Infusion 150 mg "CTH" * *Discontinued from marketing	Trastuzumab (Genetical Recombination) [Trastuzumab Biosimilar 1]	Treatment of unresectable advanced or recurrent gastric cancer with HER2 overexpression	Monoclonal antibody
January 19, 2018	11	Enbrel	Etanercept BS 10 mg for S.C. Inj. "MA" Etanercept BS 25 mg for S.C. Inj. "MA" Etanercept BS 25 mg Syringe 0.5 mL for S.C. Inj. "MA" Etanercept BS 50 mg Syringe 1.0 mL for S.C. Inj. "MA" Etanercept BS 25 mg PEN 0.5 mL for S.C. Inj. "MA" * Etanercept BS 50 mg PEN 1.0 mL for S.C. Inj. "MA" (Mochida Pharmaceutical Co., Ltd.) *Approved in 2019	Etanercept (Genetical Recombination) [Etanercept Biosimilar 1]	Treatment of rheumatoid arthritis (including the prevention of structural joint damage) and polyarticular-course juvenile idiopathic arthritis in patients who have not responded sufficiently to conventional therapies	Fusion protein
September 27, 2017	10	Rituxan	Rituximab BS Intravenous Infusion 100 mg [KHK] Rituximab BS Intravenous Infusion 500 mg [KHK] (Sandoz K.K.)	Rituximab (Genetical Recombination) [Rituximab Biosimilar 1]	Treatment of CD20-positive B-cell non-Hodgkin's lymphoma, CD20-positive B-cell lymphoproliferative disorder associated with immunosuppression, Wegener's granulomatosis, and microscopic polyangiitis	Monoclonal antibody
September 27, 2017	9	Remicade	Infliximab BS for I.V. Infusion 100 mg "Nichiiko" (Nichi-Iko Pharmaceutical Co., Ltd.) Infliximab BS for I.V. Infusion 100 mg "AYUMI" (Ayumi Pharmaceutical Corp.)	Infliximab (Genetical Recombination) [Infliximab Biosimilar 2]	Treatment of rheumatoid arthritis, psoriasis, Crohn's disease, and ulcerative colitis	Monoclonal antibody
March 28, 2016	8	Lantus	Insulin Glargine BS Injection Kit "FFP" Insulin Glargine BS Injection 100 Unit/mL "FFP" (FUJIFILM Toyama Chemical Co., Ltd.)	Insulin glargine (Genetical Recombination) [Insulin Glargine Biosimilar 2]	Treatment of diabetes mellitus where insulin therapy is indicated	Hormone

December 26, 2014	7	Lantus	Insulin Glargine BS Inj. Cartridges [Lilly] Insulin Glargine BS Inj. MirioPen [Lilly] (Eli Lilly Japan K.K.)	Insulin glargine (Genetical Recombination) [Insulin Glargine Biosimilar 1]	Treatment of diabetes mellitus where insulin therapy is indicated	Hormone
July 4, 2014	6	Remicade	Infliximab BS for I.V. Infusion 100 mg “NK” (Celltrion Healthcare Japan K.K.) Infliximab BS for I.V. Infusion 100 mg “CTH” * *Discontinued from marketing	Infliximab (Genetical Recombination) [Infliximab Biosimilar 1]	Treatment of rheumatoid arthritis in patients who have not responded sufficiently to conventional treatments (including prevention of structural joint damage), the treatment and maintenance therapy of Crohn’s disease (for use only in patients in an active phase of moderate to severe Crohn’s disease or with external fistula who have not responded sufficiently to conventional treatments), or the treatment of moderate to severe ulcerative colitis (for use only in patients who have not responded sufficiently to conventional treatments)	Monoclonal antibody
March 24, 2014	5	Gran	Filgrastim BS Inj.75 μg Syringe “Sandoz” * Filgrastim BS Inj.150 μg Syringe “Sandoz” * Filgrastim BS Inj.300 μg Syringe “Sandoz” * *Discontinued from marketing	Filgrastim (Genetical Recombination) [Filgrastim Biosimilar 3]	Mobilization of hematopoietic stem cells to peripheral blood, promotion of increase in neutrophil count at the time of hematopoietic stem cell transplantation, and the treatment of neutropenia caused by cancer chemotherapy, neutropenia which affects the treatment of human immunodeficiency virus (HIV) infection, neutropenia associated with myelodysplastic syndrome, neutropenia associated with aplastic anemia and congenital/idiopathic neutropenia	Cytokine
February 28, 2013	4	Gran	Filgrastim BS Inj. 75 μg Syringe “NK” Filgrastim BS Inj. 150 μg Syringe “NK” Filgrastim BS Inj. 300 μg Syringe “NK” (Nippon Kayaku Co., Ltd.) Filgrastim BS Injection 75 μg Syringe “NIG” * Filgrastim BS Injection 150 μg Syringe “NIG” * Filgrastim BS Injection 300 μg Syringe “NIG” * *Discontinued from marketing	Filgrastim (Genetical Recombination) [Filgrastim Biosimilar 2]	Mobilization of hematopoietic stem cells to peripheral blood, promotion of increases in neutrophil count at the time of hematopoietic stem cell transplantation, and the treatment of neutropenia caused by cancer chemotherapy, neutropenia which affects the treatment of human immunodeficiency virus (HIV) infection, neutropenia associated with myelodysplastic syndrome, neutropenia associated with aplastic anemia, and congenital/idiopathic neutropenia	Cytokine
November 21, 2012	3	Gran	Filgrastim BS Injection 75 μg Syringe “Mochida” * Filgrastim BS Injection 150 μg Syringe “Mochida” * Filgrastim BS Injection 300 μg Syringe “Mochida” * *Discontinued from marketing Filgrastim BS Injection 75 μg Syringe “F” Filgrastim BS Injection 150 μg Syringe “F” Filgrastim BS Injection 300 μg Syringe “F” (Fuji Pharma Co., Ltd.)	Filgrastim (Genetical Recombination) [Filgrastim Biosimilar 1]	Mobilization of hematopoietic stem cells to peripheral blood, promotion of increases in neutrophil count at the time of hematopoietic stem cell transplantation, and the treatment of neutropenia caused by cancer chemotherapy, neutropenia which affects the treatment of human immunodeficiency virus (HIV) infection, neutropenia associated with myelodysplastic syndrome, neutropenia associated with aplastic anemia, and congenital/idiopathic neutropenia	Cytokine
January 20, 2010	2	Espo	Epoetin Alfa BS Injection 750 syringe [JCR] Epoetin Alfa BS Injection 1500 syringe [JCR] Epoetin Alfa BS Injection 3000 syringe [JCR] Epoetin Alfa BS Injection 750 [JCR] Epoetin Alfa BS Injection 1500 [JCR]* Epoetin Alfa BS Injection 3000 [JCR]* (JCR Pharmaceuticals Co., Ltd.) *Discontinued from marketing	Epoetin kappa (Genetical Recombination) [Epoetin Alfa Biosimilar 1]	Treatment of renal anemia in patients on dialysis and anemia of prematurity	Erythropoiesis stimulating agent
June 22, 2009	1	Genotropin	Somatropin BS S.C. Injection 5 mg [Sandoz] * Somatropin BS S.C. Injection 10 mg [Sandoz]* Somatropin BS S.C. Injection 5 mg [SANDOZ] SurePal** Somatropin BS S.C. Injection 10 mg [SANDOZ] SurePal** (Sandoz K.K.) *Discontinued from marketing **Approved in 2015	Somatropin (Genetical Recombination)	Treatment of growth disturbance due to growth hormone deficiency before epiphyseal closure and growth disturbance associated with Turner syndrome or chronic renal insufficiency before epiphyseal closure	Hormone