

## Biosimilar medicines authorised via the EMA



Table last updated on 4/02/2021

based on last CHMP meeting highlights: 25-29 January 2021

[www.biosimilars-nederland.nl](http://www.biosimilars-nederland.nl)

Biosimilar	CHMP positive opinion	Indication	Marketing Authorisation Holder	Authorised*
Bevacizumab (Oyavas®)	jan-21	Colorectal Neoplasms, Breast Neoplasms, Carcinoma, Non-Small-Cell Lung, Carcinoma, Renal Cell, Uterine Cervical Neoplasms	STADA Arzneimittel AG	Pending EC decision
Bevacizumab (Alymsys®)	jan-21	Colorectal Neoplasms, Breast Neoplasms, Carcinoma, Non-Small-Cell Lung. Carcinoma, Renal Cell, Uterine Cervical Neoplasms	Mabxience Research SL	Pending EC decision
Insulin aspart (Kixelle®)	dec-20	Treatment of diabetes mellitus	Mylan IRE Healthcare Limited	Pending EC decision
Adalimumab (Yuflyma®)	dec-20	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Celltrion Healthcare Hungary Kft.	Pending EC decision
Bevacizumab (Onbevzi®)	nov-20	Colorectal Neoplasms, Breast Neoplasms, Carcinoma, Non-Small-Cell Lung, Carcinoma, Renal Cell, Uterine Cervical Neoplasms	Samsung Bioepis NL B.V.	Pending EC decision
Pegfilgrastim (Nyvepria®)	sep-20	Neutropenia	Pfizer Europe MA EEIG	nov-20
Bevacizumab (Equidacent®)	jul-20	Colorectal Neoplasms, Breast Neoplasms, Carcinoma, Non-Small-Cell Lung, Carcinoma, Renal Cell, Uterine Cervical Neoplasms	Centus Biotherapeutics Europe Limited	sep-20
Teriparatide (Livogiva®)	jun-20	Treatment of osteoporosis	Theramex Ireland Limited	aug-20
Bevacizumab (Aybintio®)	jun-20	Colorectal Neoplasms, Breast Neoplasms, Carcinoma, Non-Small-Cell Lung, Carcinoma, Renal Cell, Uterine Cervical Neoplasms	Samsung Bioepis NL B.V.	aug-20
Insulin aspart (Insulin aspart Sanofi®)	apr-20	Treatment of diabetes mellitus	sanofi-aventis groupe	jun-20
Trastuzumab (Zercepac)	mei-20	Treatment of breast and gastric cancer	Accord Healthcare S.L.U.	jul-20
Etanercept (Nepexto®)	mar/20	The treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis (ankylosing spondylitis, non-radiographic axial spondyloarthritis), plaque psoriasis and paediatric plaque psoriasis.	Mylan IRE Healthcare Limited	mei-20
Rituximab (Ruxience®)	jan-20	The treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis, and Pemphigus vulgaris.	Pfizer Europe MA EEIG	apr-20
Adalimumab (Amsparity®)	dec-19	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Pfizer Europe MA EEIG	feb-20

## Biosimilar medicines authorised via the EMA

Table last updated on 4/02/2021

based on last CHMP meeting highlights: 25-29 January 2021

Biosimilar	CHMP positive opinion	Indication	Marketing Authorisation Holder	Authorised*
Pegfilgrastim (Cegfila®)	okt-19	Neutropenia	Mundipharma Biologics S.L.	dec-19
Pegfilgrastim (Grasustek®)	apr-19	Neutropenia	Juta Pharma GmbH	apr-19
Adalimumab (Idacio®)	jan-19	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Fresenius Kabi	apr-19
Bevacizumab (Zirabev®)	dec-18	Colorectal Neoplasms, Breast Neoplasms, Carcinoma, Non-Small-Cell Lung, Carcinoma, Renal Cell, Uterine Cervical Neoplasms	Pfizer	feb-19
Trastuzumab (Ogivri®)	okt-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Mylan	dec-18
Pegfilgrastim (Fulphila®)	sep-18	Neutropenia	Mylan	nov-18
Pegfilgrastim (Pelmeg®)	sep-18	Neutropenia	Cinfa Biotech S.L.	nov-18
Pegfilgrastim (Ziextenzo®)	sep-18	Neutropenia	Sandoz	nov-18
Pegfilgrastim (Pelgraz®)	jul-18	Neutropenia	Accord Healthcare	sep-18
Pegfilgrastim (Udenyca®)	jul-18	Neutropenia	ERA Consulting	sep-18
Adalimumab (Hulio®)	jul-18	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Mylan	sep-18
Adalimumab (Halimatoz®)	mei-18	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and paediatric uveitis	Sandoz	jul-18
Adalimumab (Hefiya®)	mei-18	Juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, uveitis and paediatric uveitis	Sandoz	jul-18
Adalimumab (Hyrimoz®)	mei-18	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis, uveitis and paediatric uveitis	Sandoz	jul-18

## Biosimilar medicines authorised via the EMA

Table last updated on 4/02/2021

based on last CHMP meeting highlights: 25-29 January 2021

Biosimilar	CHMP positive opinion	Indication	Marketing Authorisation Holder	Authorised*
Trastuzumab (Trazimera®)	mei-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Pfizer	jul-18
Infliximab (Zessly®)	mrt-18	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Sandoz	mei-18
Trastuzumab (Kanjinti®)	mrt-18	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Amgen	mei-18
Insulin glargine (Semalee®)	jan-18	Diabetes Mellitus	Mylan	mrt-18
Trastuzumab (Herzuma®)	dec-17	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Celltrion	feb-18
Bevacizumab (Mvasi®)	nov-17	Fallopian tube neoplasms, Non-Small-Cell Lung Carcinoma, ovarian neoplasms, Renal Cell Carcinoma, Peritoneal Neoplasms, Breast Neoplasms	Amgen	jan-18
Trastuzumab (Ontruzant®)	sep-17	Metastatic breast cancer, early breast cancer and metastatic gastric cancer	Samsung Bioepis	nov-17
Adalimumab (Imraldi®)	jun-17	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis and uveitis	Samsung Bioepis	aug-17
Insulin Lispro (Insulin lispro Sanofi®)	may-17	Diabetes mellitus	Sanofi	jul-17
Rituximab (Blitzima®)	may-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, granulomatosis with polyangiitis and microscopic polyangiitis.	Celltrion	jul-17
Rituximab (Ritemvia®)	may-17	Non-Hodgkin's lymphoma, granulomatosis with polyangiitis and microscopic polyangiitis.	Celltrion	jul-17
Etanercept (Erelzi®)	apr-17	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, paediatric plaque psoriasis.	Sandoz	jun-17
Rituximab (Rixathon®)	apr-17	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Sandoz	jun-17
Rituximab (Riximyo®)	apr-17	Non-Hodgkin's lymphoma, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Sandoz	jun-17

## Biosimilar medicines authorised via the EMA



Table last updated on 4/02/2021

based on last CHMP meeting highlights: 25-29 January 2021

[www.biosimilars-nederland.nl](http://www.biosimilars-nederland.nl)

Biosimilar	CHMP positive opinion	Indication	Marketing Authorisation Holder	Authorised*
Adalimumab (Amgevita®)	jan-17	Rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis and uveitis	Amgen	mrt-17
Rituximab (Truxima®)	dec-16	Non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	Celltrion	feb-17
Teriparatide (Movymia®)	nov-16	Osteoporosis	STADA Arzneimittel	jan-17
Teriparatide (Terrosa®)	nov-16	Osteoporosis	Gedeon Richter	jan-17
Enoxaparin (Inhixa®)	jul-16	Prophylaxis of venous thromboembolic disease, deep vein thrombosis, pulmonary embolism, acute coronary syndrome and extra corporeal haemodialysis	Techdow	sep-16
Infliximab (Flixabi®)	mrt-16	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Samsung Bioepis	mei-16
Etanercept (Benepali®)	nov-15	Rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and plaque psoriasis	Samsung Bioepis	jan-16
Filgrastim (Accofil®)	jul-14	Neutropenia	Accord Healthcare	sep-14
Insulin glargine (Abasaglar®)	jun-14	Diabetes Mellitus	Eli Lilly	sep-14
Follitropin alfa (Bemfola®)	jan-14	Anovulation	Finox	mrt-14
Filgrastim (Grastofil®)	jul-13	Neutropenia	Apotex	okt-13
Follitropin alfa (Ovaleap®)	aug-13	Anovulation	Teva	sep-13
Infliximab (Inflectra®)	jun-13	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Hospira	sep-13
Infliximab (Remsima®)	jun-13	Rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, paediatric ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	Celltrion	sep-13
Filgrastim (Nivestim®)	mrt-10	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Hospira/Pfizer	jun-10
Filgrastim (Filgrastim Hexal®)	nov-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Hexal	feb-09
Filgrastim (Zarzio®)	nov-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Sandoz	feb-09

## Biosimilar medicines authorised via the EMA

Table last updated on 4/02/2021

based on last CHMP meeting highlights: 25-29 January 2021



[www.biosimilars-nederland.nl](http://www.biosimilars-nederland.nl)

Biosimilar	CHMP positive opinion	Indication	Marketing Authorisation Holder	Authorised*
Filgrastim (Ratiograstim®)	jul-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Ratiopharm	sep-08
Filgrastim (Tevagrastim®)	jul-08	Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer	Teva	sep-08
Epoetin zeta (Retacrit®)	oct-07	Anaemia, kidney Failure, chronic blood transfusion, autologous cancer	Hospira	dec-07
Epoetin zeta (Silapo®)	oct-07	Anaemia, kidney Failure, chronic blood transfusion, autologous cancer	Stada	dec-07
Epoetin alfa (Abseamed®)	okt-08	Anaemia, chronic renal failure, cancer	Medice	aug-07
Epoetin alfa (Binocrit®)	jun-07	Anaemia, chronic renal failure, cancer	Sandoz	aug-07
Epoetin alfa (Epoetin Alfa Hexal®)	jun-07	Anaemia, chronic renal failure, cancer	Hexal	aug-07
Somatropin (Omnitrope®)	jun-03	Growth hormone deficiency, Prader-Willi syndrome, Turner syndrome, chronic renal insufficiency, small for gestational age	Sandoz	apr-06