

Sandoz Biosimilar Portfolio and Pipeline " >

Sandoz, a Novartis division, has a leading biosimilar portfolio and pipeline in immunology, oncology and endocrinology.

- [Portfolio](#)
- [Pipeline](#)
- [Immunology](#)
- [Endocrinology](#)
- [Oncology](#)

Sandoz biosimilar	Indication area
Omnitrope® [somatropin]	Endocrinology
Erelzi® [etanercept]	Immunology (rheumatology, dermatology)
Binocrit® [epoetin alfa]	Oncology (supportive cancer care)
Zarzio®/ Zarxio® [filgrastim]	Oncology (supportive cancer care)
Ziextenzo® [pegfilgrastim]	Oncology (supportive cancer care)
Rixathon® [rituximab]	Oncology (blood cancers), Immunology (rheumatology)
Hyrimoz® [adalimumab]	Immunology (rheumatology, gastroenterology, dermatology)
Zessly® [infliximab]	Immunology (rheumatology, gastroenterology, dermatology)

In-House

Project/Compound	Submission Status	Current Phase	News Update
GP2411 (denosumab)	In Phase III	Phase III	First patient enrolled July 2019
SOK583A1 (aflibercept)	In Phase III	Phase III 1/4	First patient enrolled June 2021

Project/Compound	Submission Status	Current Phase	News Update
------------------	-------------------	---------------	-------------

Collaborations

Bio-Thera Solutions, Ltd.: Sandoz entered into a commercialization agreement with Bio-Thera Solutions, Ltd. for the proposed biosimilar bevacizumab (BAT1706). Bio-Thera Solutions, Ltd. will maintain responsibility for development and manufacturing, Sandoz will have the right to commercialize the medicine upon approval in the US, Europe, Canada and selected other countries.

Polpharma Biologics: Sandoz entered into a global commercialization agreement for a proposed natalizumab biosimilar with Polpharma Biologics to commercialize and distribute the medicine in all markets upon approval, through an exclusive global license. Under the agreement, Polpharma Biologics will maintain responsibilities for development, manufacturing and supply of proposed biosimilar natalizumab. The medicine has been accepted for regulatory review by both the EMA and US FDA.

EirGenix: The agreement between Sandoz and EirGenix, Inc, a biotechnology manufacturing and development company that aspires to provide high-quality medicines for individuals and society, aims to bring to market a proposed biosimilar trastuzumab.

Gan & Lee: Under our supply and commercialization partnership with Gan & Lee, a leading insulin supplier headquartered in China with more than 20 years of experience in insulins, we are aiming to bring to market biosimilar versions of glargine, lispro and aspart insulins.

Biocon: In global partnership with Asia's premier biopharmaceuticals company in the area of immunology.

Immune system disorders affect hundreds of millions of people worldwide and can severely impact quality of life and even life expectancy^{1,2,3}. These debilitating disorders include those affecting the joints (such as rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis), the skin (such as psoriasis) and the gut (such as Crohn's disease and ulcerative colitis).

Sandoz is the long-term partner supporting rheumatologists, dermatologists and gastroenterologists in advancing patient care without compromise. Our proven expertise and experience in biosimilars, provides high-quality affordable medicines in this therapy area.

We are committed to providing life-changing immunology therapies and have a robust biosimilar immunology portfolio with Erelzi^{®4}, Hyrimoz^{®5}, Zessly^{®6} and Rixathon^{®7}.

1. Gibofsky A. Overview of epidemiology, pathophysiology, and diagnosis of rheumatoid arthritis. Am J Manag Care. 2012 Dec;18(13 Suppl):S295-302.
2. World Health Organization. Global report on psoriasis 2016. Available at: http://apps.who.int/iris/bitstream/10665/204417/1/9789241565189_eng.pdf [Accessed March 2021]
3. Gladman D et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis 2005;64:ii14-ii17 doi:10.1136/ard.2004.032482
4. European Medicines Agency. Erelzi[®] Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/medicines/human/EPAR/Erelzi> [Accessed March 2021]
5. European Medicines Agency. Hyrimoz[®] Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/hyrimoz> [Accessed March 2021]
6. European Medicines Agency. Zessly[®] Summary of Product Characteristics. Available <https://www.ema.europa.eu/en/medicines/human/EPAR/zessly> [Accessed March 2021]
7. European Medicines Agency. Rixathon[®] Summary of Product Characteristics. Available

from: <https://www.ema.europa.eu/en/medicines/human/EPAR/rixathon> [Accessed March 2021]

Endocrinology diseases fall under a broad category of over or underproduction of hormones, altered tissue response to hormones or tumors arising from endocrine tissue¹. Some of these disorders can affect metabolism such as diabetes mellitus - with steadily increasing prevalence worldwide², impair fertility and growth.

Sandoz is committed to the Endocrinology community supporting healthcare professionals and patient care givers. Sandoz is also focused on increasing physicians and patient access to broader options for high-quality biologic medicines in Endocrinology.

We currently market Omnitrope[®] (recombinant human growth hormone, rhGH, Somatropin), which was approved by the EMA in 2006, as the world's first biosimilar medicine.³

In addition, we are working on bringing multiple insulin biosimilars to the market in the next couple of years.⁴

-
1. Melmed S, et al. (eds). Williams Textbook of Endocrinology. 13th edition. Philadelphia: Elsevier; 2016
 2. World Health Organization. (2016). Global report on diabetes: executive summary. World Health Organization. <https://apps.who.int/iris/handle/10665/204874> [Accessed February 2019]
 3. European Medicines Agency. Omnitrope[®] Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/documents/product-information/omnitrope-epar-p...> [Accessed February 2019]
 4. Sandoz International GmbH. Sandoz enters into commercialization and supply agreement for insulin biosimilars, anticipating growing demand as diabetes burden rises. Available from: <https://www.sandoz.com/news/media-releases/sandoz-enters-commercializati...> [Accessed February 2019]

Cancer is one of the leading causes of death and places a significant and growing burden on healthcare systems around the world¹.

Sandoz is committed to increasing physician and patient access to broader options for quality cancer treatments that make up the foundation of cancer care. Biosimilar treatment options could free up resources, which can be redeployed for innovation, access and new interventions within healthcare systems to support and manage the burden of oncology care.

We currently market Zarzio^{®2} / Zarxio^{®2}, Binocrit^{®3} and Ziextenzo^{®4}, used in supportive cancer care and Rixathon^{®5} to treat blood cancers. Sandoz also has a robust portfolio of investigational oncology biosimilars it is bringing to market in the future.

In addition to biosimilars, Sandoz oncology medicines have a presence in more than 93 countries and provide therapy options across the 10 most prevalent tumor types including Breast cancer, Prostate cancer, Colorectal cancer, Lung cancer, Blood cancer.

With a leading global generic oncology portfolio of >50 products, from chemotherapy, via hormones and supportive care to targeted therapies, Sandoz has been manufacturing oncology treatments for over 30 years, with a strong focus on delivering medicines of the highest purity and quality and expanding our portfolio to ensure we continue to provide a comprehensive range of oncology products.

Sandoz is committed to playing a key role in achieving global healthcare goals, by pioneering new approaches to drive increased access to healthcare worldwide.

Beyond providing high-quality affordable medicines, Sandoz is also committed to improve health care infrastructures worldwide through various partnerships and dedicated teams in many countries interacting daily with health care practitioners, providers, payers and patients.

[Learn more about Novartis in oncology](#)

1. World Health Organization. World Cancer Report 2014. Available at: <http://www.who.int/mediacentre/factsheets/fs297/en/> [Accessed January 2019]
 2. European Medicines Agency. Zarzio® /Zarxio® Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/zarzio> [Accessed January 2019]
 3. European Medicines Agency. Binocrit® Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/binocrit> [Accessed January 2019]
 4. European Medicines Agency. Zarzio® Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/zarzio> [Accessed January 2019]
 5. European Medicines Agency. Rixathon® Summary of Product Characteristics. Available from: <https://www.ema.europa.eu/en/medicines/human/EPAR/rixathon> [Accessed January 2019]
-

Source URL: <https://www.sandoz.com/products-services/biopharmaceuticals/sandoz-biosimilar-portfolio-and-pipeline>

List of links present in page

- <https://www.sandoz.com/products-services/biopharmaceuticals/sandoz-biosimilar-portfolio-and-pipeline>
- [#portfolio-5741](#)
- [#pipeline-5746](#)
- [#immunology-5751](#)
- [#endocrinology-5756](#)
- [#oncology-5761](#)
- <https://www.sandoz.com/news/media-releases/sandoz-strengthens-pipeline-entering-agreement-biosimilar-bevacizumab-key-oncology-medicine>
- <https://www.sandoz.com/news/media-releases/sandoz-announces-global-deal-commercialize-proposed-biosimilar-natalizumab-key-multiple-sclerosis-medicine>
- <https://www.sandoz.com/news/media-releases/sandoz-enters-agreement-proposed-trastuzumab-biosimilar-currently-phase-iii-development-treat-selected-her2-positive-cancer-tumors>
- <https://www.sandoz.com/news/media-releases/sandoz-enters-commercialization-and-supply-agreement-insulin-biosimilars-anticipating-growing-demand-diabetes-burden-rises>
- <https://www.sandoz.com/news/media-releases/sandoz-announces-exclusive-global-collaboration-biocon-next-generation-biosimilars>
- http://apps.who.int/iris/bitstream/10665/204417/1/9789241565189_eng.pdf
- <https://www.ema.europa.eu/medicines/human/EPAR/Erelzi>
- <https://www.ema.europa.eu/en/medicines/human/EPAR/hyrimoz>
- <https://www.ema.europa.eu/en/medicines/human/EPAR/zessly>
- <https://www.ema.europa.eu/en/medicines/human/EPAR/rixathon>
- <https://apps.who.int/iris/handle/10665/204874>
- https://www.ema.europa.eu/documents/product-information/omnitrope-epar-product-information_en.pdf
- <https://www.novartis oncology.com/>
- <http://www.who.int/mediacentre/factsheets/fs297/en/>
- <https://www.ema.europa.eu/en/medicines/human/EPAR/zarzio>
- <https://www.ema.europa.eu/en/medicines/human/EPAR/binocrit>