

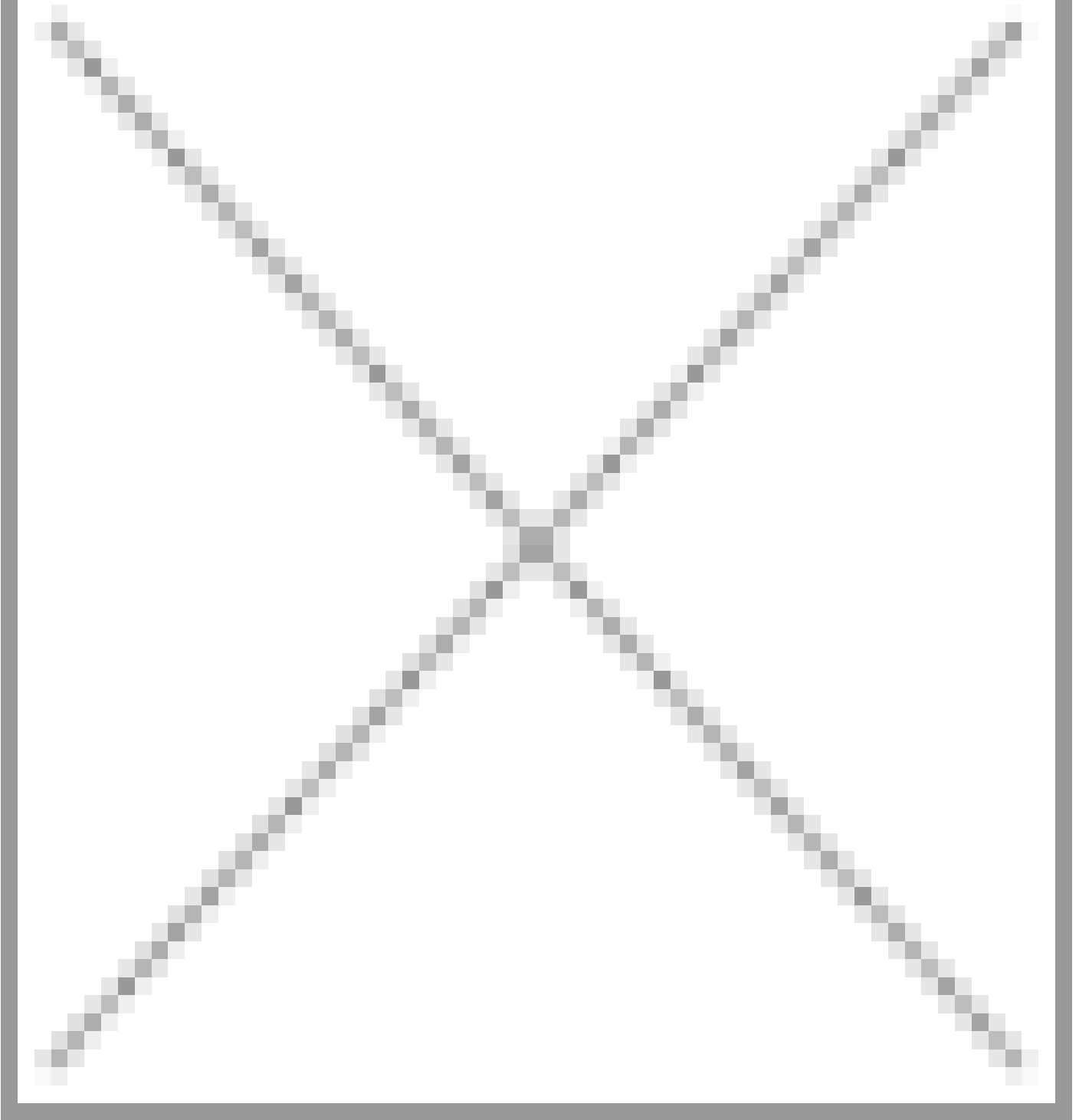
Leadership ^[1]

Sandoz is a pioneer and global leader of biosimilars^{1,2}

- 30+ years of biologic development.³
- 20+years of developing biosimilars.⁴
- 10+ years of biosimilar post-marketing surveillance.⁴

Sandoz has produced high-quality biologic products for over 35 years

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Sandoz biosimilars for erythropoietin, infliximab and rituximab have been approved and are available outside of the US only. Omnitrope®* (somatropin) was approved outside of the US as a biosimilar, but since it was submitted prior to biosimilar legislation in the US, it was approved in the US as a 505(b)(2) drug and not as a biosimilar.

* Registered trademark of Noivartis AG

Real-world experience

- More than 530 million patient-experience days with Sandoz biosimilars in almost 100

countries.^{2,11}

- Zarxio is first biosimilar in US to overtake reference biologic and become leader in market share.¹²
- Approximately \$1.2 billion in savings driven by the availability of biosimilar filgrastim from 2016 to Q1 2020, with Zarxio driving the majority of the market.¹³

Sandoz has biosimilars in various stages of development for:^{14,15}

- Dermatology
- Gastroenterology
- Nephrology
- Oncologic supportive care
- Oncology
- Rheumatology
- Endocrinology

References: 1. US Food and Drug Administration. FDA approves first biosimilar product Zarxio® [press release]; March 6, 2015. <https://wayback.archive-it.org/7993/20170111224313/http://www.fda.gov/Ne...> [2]. Accessed April 17, 2020. 2. Data on file. Sandoz Inc. February 2020. 3. BioProcess International. A decade of microbial fermentation. <https://bioprocessintl.com/upstream-processing/fermentation/a-decade-of-...> [3]. Published June 1, 2012. Accessed October 7, 2020. 4. US Food and Drug Administration. FDA Oncologic Drugs Advisory Committee Meeting: January 7, 2015. <https://wayback.archive-it.org/7993/20170404153112/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drug...> [5]. Accessed October 7, 2020. 5. Pmlive.com. This month in 1996: Ciba-Geigy and Sandoz merge. http://www.pmlive.com/pharma_news/this_month_in_1996_ciba-geigy_and_sand... [6]. Published March 17, 2014. Accessed October 7, 2020. 6. Berghout A. Clinical programs in the development of similar biotherapeutic products: rationale and general principles. *Biologicals*. 2011;39(5):293-296. 7. EMA European Medicines Agency. Somatropin. Authorisation details. <https://www.ema.europa.eu/en/medicines/human/EPAR/omnitrope> [7]. Accessed October 7, 2020. 8. *lexology.com*. FDA accepts the first biosimilar application under the BPCIA. <http://www.lexology.com/library/detail.aspx?g=4198c549-d545-4dab-ba1e-47...> [8]. Accessed October 7, 2016. 9. FDA Biosimilar Approval August 30, 2016 [press release]. US Food and Drug Administration. <https://www.fda.gov/news-events/press-announcements/fda-approves-erelzi-...> [9]. Published August 30, 2016. Accessed October 7, 2020. 10. Biosimilar Product Information. US Food and Drug Administration. <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information> [10]. Accessed September 18, 2020. 11. Data on file. Periodic Safety Update Reports. Sandoz Inc. 12. Data on file. Zarxio® Market Share Analysis. Sandoz Inc. January 2019. 13. Data on file. Filgrastim Net Sales Sandoz Inc. September 2020. 14. Data on file. Patient days of exposure. Sandoz Inc. July 2018. 15. Sandoz. Sandoz enters into commercialization and supply agreement for insulin biosimilars, anticipating growing demand as diabetes burden rises [press release]; December 19, 2018. <https://www.sandoz.com/news/media-releases/sandoz-enters-commercializati...> [11]. Accessed October 7, 2020.

Accordion Type:

- Collapsible

Source URL: <https://www.us.sandoz.com/our-work/biosimilars/leadership>

Links

[1] <https://www.us.sandoz.com/our-work/biosimilars/leadership>

[2] <https://wayback.archive-it.org/7993/20170111224313/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm>

[3] <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm>

[3] <https://bioprocessintl.com/upstream-processing/fermentation/a-decade-of-microbial-fermentation-331179>

[4] <https://wayback.archive-it.org/7993/20170404153112/https://>

[5]

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCo>

[6] http://www.pmlive.com/pharma_news/this_month_in_1996_ciba-geigy_and_sandoz_merge_553502

[7] <https://www.ema.europa.eu/en/medicines/human/EPAR/omnitrope>

[8] <http://www.lexology.com/library/detail.aspx?g=4198c549-d545-4dab-ba1e-472038ffe42a>

[9] <https://www.fda.gov/news-events/press-announcements/fda-approves-erelzi-biosimilar-enbrel>

[10] <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information>

[11] <https://www.sandoz.com/news/media-releases/sandoz-enters-commercialization-and-supply-agreement-insulin-biosimilars>