

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Sandoz resubmits biosimilar pegfilgrastim application to US FDA

- *Sandoz pursues US approval for biosimilar pegfilgrastim, a long-acting version of supportive oncology medicine filgrastim*
- *Pegfilgrastim is used to reduce the incidence of neutropenia, one of the most serious side effects of chemotherapy, hospitalizing 60,000 US cancer patients each year¹*
- *Sandoz is committed to fostering biosimilar competition, to offer high-quality, cost-effective medicines and contribute to a more sustainable healthcare system*

Holzkirchen, April 3, 2019 – Sandoz, a Novartis division and a global leader in biosimilars, today announced resubmission of its Biologics License Application (BLA) for a proposed biosimilar pegfilgrastim to the US Food and Drug Administration (FDA) to address an FDA complete response letter received in June 2016.

Pegfilgrastim is a long-acting version of filgrastim and may be prescribed to appropriate cancer patients undergoing chemotherapy to enhance the production of infection-fighting white blood cells².

Studies have shown that, each year in the US, 4,000 cancer patients die of febrile neutropenia and 60,000 are hospitalized due to neutropenia¹. Biosimilars help create the potential to save the US healthcare system up to USD 54 billion over 10 years³. Access to more treatment options for neutropenia is urgently needed, as cancer-related neutropenia hospitalizations can amount to as much as USD 2.3 billion in costs per year⁴.

“For the tens of thousands of US cancer patients undergoing chemotherapy, treatment options that can be individualized right from the start, such as long- and short-acting filgrastim biosimilars, are key to help manage the risk of serious complications related to infection,” said Mark Levick, MD, PhD, Global Head of Development, Biopharmaceuticals, Sandoz.

He added: “The US market is just beginning to benefit from biosimilars, as shown by the success of our filgrastim, the first approved biosimilar in the US. The submission of our pegfilgrastim biosimilar application is another step for us as we continue to lead the way in creating early and expanded patient access to life-changing biologics.”

Sandoz biosimilar pegfilgrastim is designed to match the reference medicine. Sandoz is pursuing approval of biosimilar pegfilgrastim to decrease the incidence of infection, as manifested by febrile neutropenia (low white blood cell count with a fever), in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia^{2,5}.

The resubmission includes new data from a pivotal pharmacokinetics (PK) and pharmacodynamics (PD) study. This was a single-dose, three-period cross-over study

comparing Sandoz pegfilgrastim with US-sourced reference pegfilgrastim; Sandoz pegfilgrastim with EU-sourced reference pegfilgrastim; and US with EU-sourced reference pegfilgrastim⁶.

Sandoz is focused on strengthening its portfolio in oncology care and remains well-positioned as a leader in the biosimilars industry based on its experience and capabilities in development, manufacturing and commercialization. Sandoz has three approved biosimilars in the US and markets eight biosimilars in the European Economic Area (EEA), including biosimilar pegfilgrastim.*

About Sandoz Proposed Biosimilar Pegfilgrastim

Pegfilgrastim is a biosimilar to Neulasta®† and is a long-acting version of filgrastim. Filgrastim is similar to a natural protein (granulocyte-colony stimulating factor) – also known as G-CSF – produced by a person's body. Pegfilgrastim, like filgrastim may be used to reduce the duration of neutropenia (low white blood cell count) and the occurrence of febrile neutropenia (low white blood cell count with a fever). Both neutropenia and febrile neutropenia are caused by cytotoxic chemotherapy (medicines that destroy rapidly growing cells). White blood cells are important as they help your body fight infection².

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “resubmits,” “pursues,” “committed,” “resubmission,” “proposed,” “may,” “can,” “beginning,” “another step,” “continue,” “lead the way,” “pursuing,” “focused,” “portfolio,” “well-positioned,” “potential,” “will,” “expect,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for biosimilar pegfilgrastim and the other investigational and approved biosimilar products described in this press release, or regarding potential future revenues from biosimilar pegfilgrastim and such other biosimilar products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that biosimilar pegfilgrastim will be approved by the FDA based on this resubmission, or at any particular time. Neither can there be any guarantee that the other investigational and approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that, if approved, biosimilar pegfilgrastim or such other biosimilar products will be approved for all indications included in the reference product's label. Neither can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding biosimilar pegfilgrastim and such other products could be affected by, among other things, regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; the particular prescribing preferences of physicians and patients; competition in general, including approval of additional biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political and economic conditions; safety, quality or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars and a pioneer in the emerging field of prescription digital therapeutics. Our purpose is to pioneer access to healthcare by developing and commercializing novel, affordable approaches that address unmet medical need. Our broad portfolio of high-quality medicines, covering all major therapeutic areas and increasingly focused on value-adding differentiated medicines, accounted for 2018 sales of USD 9.9 billion. Sandoz is headquartered in Holzkirchen, in Germany's Greater Munich area.

Sandoz is on Twitter. Sign up to follow @Sandoz_global at http://twitter.com/Sandoz_Global.

References

1. Centers for Disease Control and Prevention (CDC). Cost of Cancer-Related Neutropenia or Fever Hospitalizations. Available at: <https://www.cdc.gov/cancer/dcpc/research/articles/neutropenia.htm>. Accessed January 16, 2019.
2. European Medicines Agency. Ziextenzo European Public Assessment Report. Available at: <https://www.ema.europa.eu/medicines/human/EPAR/ziextenzo/product-information-section>. Accessed October 8, 2018.
3. Mulcahy AW, Hlávka JP, Case SR. Biosimilar cost savings in the United States: initial experience and future potential. Santa Monica, CA: Rand Corporation, 2017.
4. Tai E, Guy GP, Dunbar A, Richardson LC. Cost of cancer-related neutropenia or fever hospitalizations, United States, 2012. *Journal of Oncology Practice* 2017;13(6):e552–e561.
5. Neulasta Full Prescribing Information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125031s189s191lbl.pdf. Accessed February 22, 2019.
6. R Nakov, S Schussler, S Schier-Mumzhiu, A Skerjanec, A Bellon, J Wang, A Krendyukov, G Otto; 1796P A large multi-center, randomized, double-blind, crossover study in healthy volunteers to compare pharmacokinetics and pharmacodynamics of a proposed biosimilar pegfilgrastim with EU and US reference pegfilgrastim: Methodological approach, *Annals of Oncology*, Volume 29, Issue suppl_8, 1 October 2018, mdy300.110, <https://doi.org/10.1093/annonc/mdy300.110>.

†Neulasta® is marketed by and is a registered trademark of Amgen, Inc.

*European Economic Area (EEA). The European Economic Area (EEA) provides for the free movement of persons, goods, services and capital within the internal market of the European Union (EU) between its 28 member states, as well as three of the four member states of the European Free Trade Association (EFTA): Iceland, Liechtenstein and Norway.

#

For further information, contact:

Novartis Media Relations

Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com
Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Chris Lewis
Sandoz Global Communications
+49 174 244 9501 (mobile)
chris.lewis@sandoz.com

Annick Lambert
Sandoz US Communications
1 609 480 8756 (mobile)
annick.lambert@sandoz.com

Novartis Investor Relations

Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central

Samir Shah	+41 61 324 7944
Pierre-Michel Bringer	+41 61 324 1065
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

North America

Richard Pulik	+1 212 830 2448
Cory Twining	+1 212 830 2417