Sandoz receives positive CHMP opinion for proposed biosimilar pegfilgrastim

- Positive opinion is based on comprehensive data confirming that Sandoz biosimilar pegfilgrastim matches the reference medicine in terms of safety, efficacy and quality.
- Sandoz seeks approval in the same indication as the reference medicine, to reduce the duration of neutropenia and the incidence of febrile neutropenia due to chemotherapy, some of the most serious side effects of cancer chemotherapy.
- Sandoz is the global leader in biosimilars and continues to improve patient access and support sustainable healthcare with seven approved biosimilars.

Holzkirchen, September 21, 2018 – Sandoz, a Novartis division and the pioneer and global leader in biosimilars, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for marketing authorization of its proposed biosimilar pegfilgrastim, a long-acting version of supportive oncology care medicine filgrastim.

"The burden of cancer and its treatment – specifically chemotherapy – is something Sandoz has worked tirelessly to address for more than three decades," said Mark Levick MD, PhD, Global Head of Development, Biopharmaceuticals, Sandoz.

"While pegfilgrastim is a proven effective and safe treatment for febrile neutropenia-related infections, many cancer patients throughout Europe are not treated with this medicine. Our biosimilar medicine is expected to match the reference medicine in terms of safety, efficacy and quality. If approved, we will do our best to provide this critically-important option to all patients who stand to benefit from it."

Sandoz is committed to increasing patient access to high-quality biosimilars, with five marketed and seven approved biosimilars in Europe.

Pegfilgrastim is a long-acting form of filgrastim, a biosimilar medicine that stimulates the production of white blood cells and stem cells. Sandoz is seeking approval for use of biosimilar pegfilgrastim in the same indication as the reference medicine, to reduce the duration of neutropenia and the incidence of febrile neutropenia due to chemotherapy. The comprehensive data package, submitted as part of the Marketing Authorization Application, includes analytical, preclinical, and clinical data, which demonstrate that Sandoz biosimilar pegfilgrastim matches the reference medicine in terms of safety, efficacy and quality.

Febrile neutropenia is a serious and possibly life-threatening condition that can develop in people with cancer who receive chemotherapy. Despite treatment advances, febrile neutropenia may pose risks to a person’s chemotherapy treatment plan, with consequences such as dose reductions, discontinuation of treatment or changing to a less effective regimen.

The European Commission (EC) takes binding decisions on the authorization of medicines valid throughout the EU. It bases its decisions on scientific assessments by the CHMP, ensuring that medicines comply with high quality, safety and efficacy standards. If approved by the EC, the centralized marketing authorization will be valid in the 28 countries that are members of the EU. Norway, Iceland and Liechtenstein, as members of the European Economic Area (EEA), will take corresponding decisions based on the EC’s recommendation.
About pegfilgrastim

Pegfilgrastim is a long-acting version of filgrastim and belongs to a group of proteins called cytokines. It is similar to a natural protein (granulocyte-colony stimulating factor) produced by a person’s own body, and 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). Febrile neutropenia is caused by cytotoxic chemotherapy (medicines that destroy rapidly growing cells); white blood cells are important as they help your body fight infection. Preventing febrile neutropenia is essential because the condition itself can delay and interrupt cancer treatment, and cause serious infections, such as sepsis, and ultimately death.²

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 “positive opinion,” “recommendation,” “proposed,” “potential,” “can,” “will,” “believe,” “committed,” “investigational,” “portfolio,” “launch,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved biosimilar products described in this press release, or regarding potential future revenues from such 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 the investigational or 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. Neither can there be any guarantee that, if approved, such biosimilar products will be approved for all indications included in the reference product’s label. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential 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; 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 is a global leader in generic pharmaceuticals and biosimilars. As a division of the Novartis Group, our purpose is to discover new ways to improve and extend people’s lives. We contribute to society’s ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Our portfolio of approximately 1,000 molecules, covering all major therapeutic areas, accounted for 2017 sales of USD 10.1 billion. In 2017, our products reached well over 500 million patients. 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](http://twitter.com/Sandoz_Global).

Follow our blog at [www.sandoz.com/makingaccesshappen](http://www.sandoz.com/makingaccesshappen).

References


®†*Neulasta® 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.

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