Sandoz receives eighth European Commission approval for a biosimilar with Ziextenzo® (pegfilgrastim)

- **Biosimilar Ziextenzo® (pegfilgrastim),** a long-acting version of supportive oncology medicine filgrastim, is now approved for use in all reference medicine indications.
- Ziextenzo is indicated to reduce duration of neutropenia / incidence of febrile neutropenia, some of the most serious side effects of chemotherapy.
- Sandoz demonstrates commitment to making access happen for patients with eight biosimilars approved in EU, including five in last 18 months.

**Holzkirchen, November 27, 2018** – Sandoz, a Novartis division and the pioneer and global leader in biosimilars, today announced that the European Commission (EC) granted marketing authorization for biosimilar Ziextenzo® (pegfilgrastim).

Ziextenzo is indicated to reduce the duration of neutropenia and incidence of febrile neutropenia in adult patients treated with cytotoxic (anti-cancer) chemotherapy for malignancy with the exception of chronic myeloid leukemia and myelodysplastic syndromes. These indications match those of the reference medicine.\(^1\)\(^3\)

"Despite advancements in cancer treatment, febrile neutropenia remains one of the most significant complications of chemotherapy and is a major cause of morbidity," said Stefan Hendriks, Global Head of Biopharmaceuticals, Sandoz. "With the approval of Ziextenzo, a long-acting version of oncology supportive medicine filgrastim, we look forward to providing a treatment option that delivers the possibility of further reducing both the personal and financial burden of cancer."

This approval was based on comprehensive analytical, preclinical and clinical data. In these studies, Ziextenzo matched the reference medicine in terms of safety, efficacy and quality. Pegfilgrastim, the active substance in Ziextenzo, is a long-acting form of filgrastim, which stimulates the production of white blood cells.\(^1\)

"Pegfilgrastim biosimilars, such as Ziextenzo, mark a true advancement for people with cancer. These medicines help deliver optimized long-acting dosing and patient convenience while creating savings for our hard-pressed health systems," said Dr. Paul Cornes, oncologist and member of the Continuing Medical Education program of the European Association of Hospital Pharmacists and Core Lecturer for the European School of Oncology, United Kingdom.

Sandoz remains committed to making access happen for patients and leads in biosimilars with eight approved biosimilars worldwide, including five in the last 18 months. We look forward to making available a robust portfolio of biosimilar medicines that enables early and expanded access for patients as well as generates healthcare savings worldwide.

**About Ziextenzo® (pegfilgrastim)**

Pegfilgrastim is a long-acting form of filgrastim. Filgrastim is very similar to a natural protein (granulocyte-colony stimulating factor) – also known as G-CSF – produced by a person's own body. 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). 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.\(^1\)
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 “focus on,” “potential,” “can,” “will,” “plan,” “expect,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “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 marketed by Amgen, Inc. in Europe. It is a registered trademark of Amgen, Inc.

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