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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Sandoz receives US FDA approval for long-acting oncology supportive care biosimilar Ziextenzo™ (pegfilgrastim-bmez)

- *Ziextenzo™ is indicated to decrease the incidence of febrile neutropenia, one of the most serious side effects of chemotherapy*
- *With approval of Ziextenzo™, Sandoz is first and only company to offer US physicians long- and short-acting filgrastim biosimilar treatment options*
- *With four US approved biosimilars, Sandoz is committed to expanding patient access, increasing healthcare savings and fueling innovation*

Holzkirchen, Nov. 5, 2019 – Sandoz, a Novartis division and a global leader in biosimilars, today announced that the US Food and Drug Administration (FDA) approved its biosimilar Ziextenzo™ (pegfilgrastim-bmez). Sandoz biosimilar pegfilgrastim has been approved and marketed in Europe as Ziextenzo® (pegfilgrastim) since 2018. Sandoz now intends to launch Ziextenzo in the US as soon as possible this year.

Ziextenzo is indicated 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.

“When a cancer patient with febrile neutropenia gets an infection, it can have serious consequences such as delays or dose reductions of chemotherapy,” said Carol Lynch, President of Sandoz Inc. “The approval of Ziextenzo expands our oncology portfolio, providing physicians with a long-acting supportive oncology biosimilar option. It builds on the foundation of trust and experience we developed with our short-acting filgrastim Zarxio® – the leading filgrastim by market share in the US – including consistent product supply and reliable patient services.”

A study has shown that each year in the US, more than 60,000 cancer patients are hospitalized with evidence of neutropenia, including fever or infection, with more than 4,000 deaths as a result.[1] Sandoz is now the first and only company to offer physicians in the US the choice between a long- and short-acting biosimilar filgrastim treatment to best suit the individual needs of tens of thousands of patients undergoing chemotherapy.

The FDA approval of Ziextenzo was based on analytical, preclinical and clinical research, including data from a pivotal three-way pharmacokinetics (PK) and pharmacodynamics (PD) study (LA-EP06-104).[2] This study compared Sandoz pegfilgrastim with US-sourced reference pegfilgrastim, Sandoz pegfilgrastim with EU-sourced reference pegfilgrastim, and US-sourced with EU-sourced reference pegfilgrastim. PK and PD similarity were demonstrated in all three comparisons, and no clinically meaningful differences were observed regarding safety and immunogenicity among the treatment groups.

Sandoz has proven biosimilars create early and expanded patient access to life-changing biologics while increasing healthcare savings. Its four approved biosimilars in the US are part of a leading global portfolio with eight marketed biosimilars. Building on this success, Ziextenzo can help increase positive treatment outcomes for patients undergoing chemotherapy and drive significant savings for the healthcare system.[2,3]

Sandoz is a global biosimilar leader and will continue to help millions of patients in oncology, immunology, endocrinology and other underserved therapy areas access biologic medicines sustainably and affordably.

About Ziextenzo (pegfilgrastim-bmez)
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. Ziextenzo is indicated in the US 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.[4] 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.[5]

Please see full Prescribing Information for Ziextenzo here.

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 “potential,” “can,” “will,” “plan,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” or similar terms, or by express or implied discussions regarding potential regulatory submissions, marketing approvals, launches, new indications or labeling for biosimilar pegfilgrastim and the other 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 or other Sandoz biosimilars will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that biosimilar pegfilgrastim will be successfully launched, or at any particular time. Nor can there be any guarantee that, if approved, any Sandoz biosimilar will be approved for all indications in the originator product label. Neither can there be any guarantee that biosimilar pegfilgrastim or other Sandoz biosimilars 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 pegfilgrastim; 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. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical need. Our ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines, covering all major therapeutic areas, 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

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