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FDA accepts Sandoz application for biosimilar filgrastim

- *Sandoz is the first company to announce it has filed for approval of a biologic under the biosimilars pathway created in the Biologics Price Competition and Innovation Act of 2009 (BPCIA).*
- *FDA's acceptance of Sandoz's filing is an important first step in increasing US patient access to affordable, high-quality biologics*
- *Sandoz is a global leader in biosimilars with over 50% share of the global biosimilars market [1]*

Holzkirchen, July 24, 2014 – Sandoz, a Novartis Group company, announced today that the US Food and Drug Administration (FDA) has accepted its Biologics License Application for filgrastim, which was filed under the new biosimilar pathway created in the Biologics Price Competition and Innovation Act of 2009 (BPCIA).

The reference product – Amgen's NEUPOGEN® – is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever.

"This filing acceptance represents a significant step toward making high-quality biologics more accessible in the US and we applaud FDA for its progress in making this a reality," said Mark McCamish, M.D., Ph.D., and Head of Global Biopharmaceutical & Oncology Injectables Development at Sandoz. "As they've done in Europe and other highly-regulated markets around the world, biosimilars are poised to increase US patient access to affordable, high-quality biologics, while reducing the financial burden on payers and the overall healthcare system."

Under the brand name ZARZIO®, the Sandoz biosimilar filgrastim has been marketed in more than 40 countries outside the US, generating nearly six million patient-exposure days of experience. ZARZIO is the number one biosimilar filgrastim globally and is the leading daily G-CSF in Europe with 30 percent volume market share.

Sandoz is a pioneer in biosimilars and the global market leader with over 50% share of all biosimilars approved in the highly-regulated markets of Canada, Europe, Japan and Australia. Sandoz currently markets three biosimilars outside the US; each of which occupies the #1 biosimilar position in its respective category. Sandoz biosimilars are sold in over 60 countries and have generated over 200 million patient-exposure days in experience. Sandoz also has an unrivalled pipeline with several molecules in various stages of development. Sandoz now has six molecules in Phase III clinical trials/filing preparation, more than any other company in the industry.

[1] Includes products approved in North America, Europe, Japan and Australia

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Disclaimer

This press release contains forward-looking statements that can be identified by words such as "first step," "poised," "pipeline," or similar terms, or by express or implied discussions regarding potential marketing approval for biosimilar filgrastim, or regarding potential future revenues from biosimilar filgrastim. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 filgrastim will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that biosimilar filgrastim will be commercially successful in the future. In particular, management's expectations regarding biosimilar filgrastim could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, 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, the generic pharmaceuticals division of Novartis, is a global leader in the generic pharmaceutical sector. Sandoz employs over 26,500 employees and its products are available in more than 160 countries, offering a broad range of high-quality, affordable products that are no longer protected by patents. With USD 9.2 billion in sales in 2013, Sandoz has a portfolio of approximately 1,100 molecules, and holds the #1 position globally in biosimilars as well as in generic injectables, ophthalmics, dermatology and antibiotics, complemented by leading positions in the cardiovascular, metabolism, central nervous system, pain, gastrointestinal, respiratory, and hormonal therapeutic areas. Sandoz develops, produces, and markets these medicines, as well as active pharmaceutical and biotechnological substances. Nearly half of Sandoz's portfolio is in differentiated products, which are defined as products that are more difficult to scientifically develop and manufacture than standard generics.

In addition to strong organic growth since consolidating its generics businesses under the Sandoz brand name in 2003, Sandoz has benefitted from strong growth of its acquisitions, which include Lek (Slovenia), Sabex (Canada), Hexal (Germany), Eon Labs (US), EBEWE Pharma (Austria), Oriel Therapeutics (US), and Fougera Pharmaceuticals (US).

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

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