Media Release | Medienmitteilung | Communiqué Aux Médias

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Sandoz biosimilar filgrastim recommended for approval by FDA Oncologic Drugs Advisory Committee

- *Oncologic Drugs Advisory Committee (ODAC) votes in favor of recommending biosimilar filgrastim for approval in the US*
- *Biosimilar filgrastim recommended to be approved for use in all requested indications*
- *Committee's recommendation based on review of extensive data from analytical, non-clinical, clinical studies and post-marketing pharmacovigilance*

Holzkirchen, January 7, 2014 – Sandoz, a Novartis company, announced today that US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) recommended approval of its investigational biosimilar filgrastim in the US. The Committee also recommended approval of the biosimilar for use in all indications included in the reference product's (Amgen's NEUPOGEN®) label.

"We are pleased with the ODAC's recommendation to approve our biosimilar filgrastim and we look forward to continuing to work with FDA as it completes its review of our filing," said Mark McCamish, M.D., Ph.D., Head of Global Biopharmaceutical & Oncology Injectables Development at Sandoz. "We are proud to lead the way in biosimilars globally and believe this positive recommendation brings us one step closer to delivering high-quality biosimilars to patients in the US."

The recommendation was provided after the presentation of a comprehensive package of nonclinical, clinical and post-marketing pharmacovigilance data which confirmed Sandoz' biosimilar filgrastim is highly similar to the reference product (Amgen's NEUPOGEN®). The pivotal clinical package included a pharmacokinetic and pharmacodynamics (PK/PD) study in healthy volunteers, which established bioequivalence, and a clinical efficacy and safety study in breast cancer patients which demonstrated the same clinical performance and safety as the reference product.

The clinical package is also supported by a global program including five randomized, double-blind, single and multiple dose PK/PD studies in healthy volunteers to assess pharmacokinetic and pharmacodynamic equivalence between biosimilar filgrastim and NEUPOGEN® and a European non-comparative clinical safety and efficacy study. Post-marketing pharmacovigilance data from countries outside of the US also contributed to the totality of evidence.

Under the brand name ZARZIO®, the Sandoz biosimilar filgrastim has been marketed in more than 40 countries outside the US, generating nearly 7.5 million patient-

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exposure days of experience. If approved in the US, Sandoz proposes to market biosimilar filgrastim under the name ZARXIO™.

FDA frequently seeks the advice of its advisory committees as it reviews and decides whether to approve treatments, although it is not obligated to follow the recommendation.

Sandoz is the global leader with over 50 percent volume 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 biosimilars pipeline with several molecules in various stages of development, including six molecules in Phase III clinical trials/registration – more than any other company in the industry.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by words such as “recommended,” “votes in favor of recommending,” “recommendation,” “investigational,” “look forward,” “believe,” “will,” or similar terms, or by express or implied discussions regarding potential future product approvals, or regarding potential revenues from biosimilar filgrastim or any potential future products. 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 additional markets, or at any particular time. Neither can there be any guarantee that any other potential future products will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that biosimilar filgrastim or any other potential future products will be commercially successful in the future. In particular, management’s expectations regarding biosimilar filgrastim and such other potential future products could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general, including approval of additional versions of biosimilar filgrastim; the company’s ability to obtain or maintain proprietary intellectual property protection, including unexpected patent litigation outcomes; government, industry and general public pricing pressures; unexpected manufacturing issues; general economic and industry conditions, 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.

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About Sandoz

Sandoz, a Novartis company, is a global leader in the generic pharmaceutical sector. Sandoz employs over 26,500 employees across 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).

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Footnotes:

1. NEUPOGEN® is a registered trademark of Amgen.
2. ZARXIO® is a registered trademark of Novartis AG.