Phase III data shows Sandoz’ investigational biosimilar filgrastim has similar safety and efficacy as Amgen’s NEUPOGEN®

- Pivotal PIONEER study compared safety and efficacy of the two compounds in the prevention of neutropenia in patients with breast cancer
- PIONEER data supported filing for biosimilar filgrastim in the US
- The abstract of the study results is published online as part of the 56th American Society of Hematology (ASH) Annual Meeting and Exposition

Holzkirchen, December 8, 2014 – Sandoz, a Novartis company, announced today Phase III data that demonstrated similarity of its investigational biosimilar filgrastim compared to the US-licensed reference product, Amgen’s NEUPOGEN® (filgrastim) in the prevention of severe neutropenia in patients with breast cancer receiving neoadjuvant myelosuppressive chemotherapy. The study also showed that repeated switching at each cycle between the investigational biosimilar and the originator filgrastim showed no impact on efficacy, safety or immunogenicity.

The PIONEER study was a Phase III study designed to compare the efficacy and safety of the investigational biosimilar and the reference product with respect to mean duration of severe neutropenia following Cycle 1 chemotherapy. PIONEER was a randomized, double-blind, four-group, multi-center non-inferiority trial conducted at 27 centers. The trial randomized 218 breast cancer patients receiving neoadjuvant myelosuppressive chemotherapy.

On July 24, Sandoz announced that the FDA accepted its application for filgrastim, making Sandoz the first company to have a filing accepted under the new US biosimilar pathway created in the Biologics Price Competition and Innovation Act of 2009 (BPCIA). The Phase III PIONEER study results supported this filing. “Biosimilars can play an important role in broadening access to high-quality biologics in the United States,” said Prof. Kimberly Blackwell, MD, Professor of Medicine, Assistant Professor of Radiation Oncology, Duke University School of Medicine. “I'm also optimistic that the savings generated through the use of biosimilars can be used to fund other unmet medical needs.”

“We are pleased by these clinical study results as they confirm the similarity of our investigational biosimilar filgrastim compared to the reference product in terms of safety and efficacy,” said Mark McCamish, M.D., Ph.D., Head of Global Biopharmaceutical & Oncology Injectables Development at Sandoz. “The data from this important study also reinforces the results we have seen in earlier stages of development including multiple Phase I, pre-clinical and analytical studies. We look forward to making this product available to patients and healthcare providers in the United States.”
Sandoz is the global market segment leader with over 50 percent volume share of all biosimilars approved in North America, 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 170 million patient-exposure days in experience. Sandoz also has a robust pipeline with six molecules in Phase III clinical trials/registration – more than any other company in the industry.

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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