Phase III data shows Sandoz’ proposed biosimilar pegfilgrastim has similar safety and efficacy as the reference product

- PROTECT 2 study compared safety and efficacy of the proposed biosimilar pegfilgrastim with the reference product for the prevention of neutropenia in patients with breast cancer.
- The study met its primary endpoints demonstrating equivalence and non-inferiority to the reference product.
- Data presented at the 57th American Society of Hematology (ASH) Annual Meeting and Exposition.

Holzkirchen, 7 December 2015 – Sandoz, a Novartis company and global leader in biosimilars, today announced results from the PROTECT 2 study which compared the safety and efficacy of proposed biosimilar pegfilgrastim with the reference product, Neulasta®. The study met its primary endpoints – showing it to be both equivalent and non-inferior to the reference product. Data was presented at the American Society of Hematology (ASH), Orlando, Florida.

Additional data from the study showed that there were no clinically meaningful differences between the proposed biosimilar pegfilgrastim and the reference product. Adverse events were similar and consistent with the known safety profile of pegfilgrastim, and no neutralizing anti-pegfilgrastim antibodies were detected.

“The positive data from the PROTECT 2 study is promising in that it will add to the body of evidence being developed on biosimilars. These findings could lead to another high-quality supportive care treatment option for physicians and oncology patients” said Kimberly Blackwell, MD, Professor of Medicine, Assistant Professor of Radiation Oncology, Duke University School of Medicine and primary investigator for the study.

Malte Peters, Head Biopharmaceutical Clinical Development, Sandoz said “The PROTECT 2 data is yet another demonstration of the substantial progress we are making with our biosimilar programs and the commitment we have made to improve patient access to these important medicines.”

Sandoz has an unwavering commitment to increasing patient access to high-quality biosimilars. It is the pioneer and global market leader in biosimilars and was the first to launch biosimilars in the United States, Europe and Japan. Sandoz has a leading biosimilar pipeline with programs in various stages of development – the company plans to make 10 regulatory filings over a three year period (2015-2017) having already announced two. On November 18, 2015, Sandoz announced that the FDA accepted its regulatory filing for the proposed biosimilar pegfilgrastim. As part of the Novartis Group, Sandoz is well-positioned to lead the biosimilars industry based on its deep experience and capabilities in development, manufacturing and commercialization.

About PROTECT 2
The PROTECT 2 study was a global, randomized, double-blind trial involving 308 patients carried out in the United States, Latin America, Asia and Europe. The safety and immunogenicity of the proposed
biosimilar was assessed for four weeks after the final study drug administration. The study analyzed the duration of severe neutropenia (DSN), which was also the primary endpoint.

**About PROTECT 1**

PROTECT 1 was a randomized, double-blind trial comparing the efficacy and safety of the proposed biosimilar pegfilgrastim (LA-EP2006) with reference pegfilgrastim in patients with breast cancer. PROTECT 1 data will be presented at San Antonio Breast Cancer Symposium, December 9, 2015 at 5 PM CST (SABCS Abstract #P1-10-01).

**Disclaimer**
The foregoing release contains forward-looking statements that can be identified by words such as "promising," "will," "could," "commitment," "pipeline," "plans," or similar terms, or by express or implied discussions regarding potential marketing submissions or approvals for pegfilgrastim, or regarding potential future revenues from pegfilgrastim. 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 pegfilgrastim will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that pegfilgrastim will receive additional regulatory approvals or be commercially successful in the future. In particular, management's expectations regarding pegfilgrastim 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; 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 or quality issues; unexpected safety 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, a Novartis company, is a global leader in generic pharmaceuticals and biosimilars, driving sustainable access to high-quality healthcare. Sandoz employs more than 26,000 people worldwide and supplies a broad range of affordable, primarily off-patent products to patients and customers around the globe. The Sandoz portfolio comprises approximately 1,100 molecules, which accounted for 2014 sales of USD 9.6 billion. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area. The company holds leading global positions in biosimilars as well as in generic anti-infectives, ophthalmics and transplantation medicines.

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