



Media Release

Medienmitteilung

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Sandoz receives positive EU opinion for biosimilar filgrastim

- *Approval would expand patient choice, in particular for those undergoing chemotherapy*
- *Sandoz further reinforces pioneer position, with third biosimilar medicine*
- *Leading Sandoz biosimilar pipeline includes two dozen further projects*

Holzkirchen, November 21, 2008 – Sandoz has received a positive opinion from European regulators for its third biosimilar medicine, filgrastim, marking another important milestone in its efforts to bring affordable high-quality biopharmaceuticals to patients worldwide.

Filgrastim is indicated for use in treating neutropenia, a condition characterized by lack of neutrophils – one of the most common types of white blood cells – that is often associated with chemotherapy or bone marrow transplants. Filgrastim is a natural man-made protein produced commercially by recombinant DNA technology, which stimulates production of white blood cells.

Sandoz CEO Andreas Rummelt says: “The positive opinion from the CHMP (Committee on Medicinal Products for Human Use) is an important first step towards receiving EU regulatory approval. Such approval would provide an important new option, in particular for patients undergoing chemotherapy.

“Filgrastim enables them to stay on their required course of therapy at the optimal dose level by raising neutrophil counts to within the normal range. In addition to significant potential cost savings, our product offers patients and healthcare providers a very pure form of filgrastim.”

This is the third time that the CHMP, which reviews medicines scientifically in the EU, has issued a positive opinion for a Sandoz biosimilar. In a precedent-setting decision in April 2006, Sandoz was the first company to obtain EU approval for such a medicine, human growth hormone Omnitrope[®]. Binocrit[®] / Epoetin alfa Hexal[®], the first follow-on erythropoetin and the first complex (glycoprotein) biosimilar, was approved in the EU in August 2007 and launched the same year. Sandoz, the biosimilars pioneer, also has a comprehensive pipeline, with two dozen projects at various stages of development.

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Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “would,” “pipeline,” “potential,” or similar expressions, or by express or implied discussions regarding potential marketing approvals for filgrastim or other biosimilar products, or regarding potential future revenues from filgrastim or other such products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that filgrastim will be approved for sale in any market, or that other biosimilar products will be submitted for approval, or approved for sale in any market. Nor can there be any guarantee that filgrastim, or such other products, will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding these products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected developmental delays, including unexpected clinical or other laboratory data; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group’s assets and liabilities as recorded in the Group’s consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. 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 Division of the Novartis group, is a global leader in the field of generic pharmaceuticals, offering a wide array of high-quality, affordable products that are no longer protected by patents. Sandoz has a portfolio of more than 950 compounds and sells its products in more than 130 countries. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments and hormone therapies. Sandoz develops, produces and markets these medicines along with pharmaceutical and biotechnological active substances and anti-infectives. In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany) and Eon Labs (US). In 2007, Sandoz employed around 23,000 people worldwide and posted sales of USD 7.2 billion.

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For further information

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