



Media Release

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Sandoz receives FDA approval for Omnitrope® Pen 10 with liquid cartridge

- *New 10mg strength offers increased treatment flexibility and more convenient dosage form*
- *Comparable quality, safety and efficacy combined with significant cost savings*
- *Approval further demonstrates Sandoz leadership in high quality follow-on biologics*

Princeton, New Jersey, September 3, 2008 -- Sandoz has received US Food and Drug Administration approval for its Omnitrope® Pen 10 with liquid cartridge. Omnitrope, a somatotropin, is approved for long-term treatment of pediatric patients who have growth failure and long-term replacement therapy in adults with growth hormone deficiency.

There are approximately 50,000 pediatric patients and 25,000 adult patients who use a somatotropin in the US.¹ The Omnitrope Pen 10 with liquid cartridge provides increased treatment flexibility for physicians and a more convenient dosage form for patients. It will also offer significant cost savings compared to the reference product, Genotropin®, and other leading recombinant growth hormones.

“The FDA approval of the 10 mg strength of Omnitrope will allow physicians to treat a broader spectrum of patients with a high quality, lower cost treatment option,” said Bernhard Hampl, chief executive officer of Sandoz Inc., the US subsidiary of Sandoz. “Follow-on biologics are a key part of the Sandoz strategy and we are committed to increasing patient access through follow-on biologics once patents have expired.”

The 10 mg version has been marketed by Sandoz in key European countries since earlier this year. A 5 mg strength version, Omnitrope Pen 5 with liquid cartridge, has been available in the US since March.

Omnitrope is highly similar to Genotropin in its safety and efficacy profiles.²

Sandoz pioneered the field of follow-on biologics with the approvals and subsequent launches of a lyophilized powder form of Omnitrope in the US and Europe. Omnitrope was the first follow-on biologic to receive approval and be made available to patients in both regions. It was the first ever medicine to be approved in the EU as a biosimilar, the European regulatory term for such products.

Follow-on biologics are a key part of the Sandoz strategy to focus on difficult-to-make generics that provide added patient benefits. Due to the rising costs of health care and the growing need for more complex treatments, they will play an increasingly important role in ensuring access to medicines. Sandoz is building a strong global pipeline of follow-on biologics, with 25 projects currently under development.

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

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "will," "rising," or similar expressions, or by express or implied discussions regarding the launch of Omnitrope Pen 10, potential future approvals of other follow-on biologic products, or regarding potential future revenues from Omnitrope Pen 10, other Omnitrope products, or from any such other follow-on biologic products. Such forward-looking statements reflect the current views of the company 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 the launch of Omnitrope Pen 10 will be successful. Nor can there be any guarantee that any other follow-on biologic products will be approved for sale. Neither can there be any guarantee that Omnitrope Pen 10, or any such other follow-on biologic products will achieve any particular levels of revenue in the future. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; an inability to obtain needed legislative changes to create new regulatory approval pathways for follow-on biologic products; competition in general; production delays or business interruption generally; government, industry and general public pricing pressures; the effect that the foregoing factors could have on the values attributed to the 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 U.S. 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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- 1 According to external data compiled by Sandoz.
- 2 FDA Citizen Petition Response Docket NOs 2004 P-0231/CP1 and SUP 1, 2003 P-0176/CP1 and EMC1, 2004 PO 171/CP1 and 2004 N-0355, May 30, 2006: at 12.

Omnitrope® is a trademark of Sandoz.
Genotropin® is a registered trademark of Pfizer.