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## **Sandoz receives approval for first-ever Japanese biosimilar**

- *Sandoz receives approval for first-ever Japanese biosimilar, recombinant human growth hormone somatropin, further reinforcing global pioneer position in field*
- *Approval paves way for greater access to high-quality biopharmaceuticals in Japan, the world's second largest pharmaceutical market*
- *Sandoz somatropin already marketed as Omnitrope<sup>®</sup> in EU, US and Australia*

**Holzkirchen, June 25, 2009** – Sandoz has received marketing authorization for the first-ever Japanese biosimilar, recombinant human growth hormone somatropin. The precedent-setting decision further reinforces Sandoz's global leadership position in the rapidly-emerging market for biosimilars, or follow-on versions of existing state-of-the-art biopharmaceuticals.

Sandoz CEO Jeff George said: "We are pleased that Sandoz, the pioneer in biosimilars and a company with a global reputation for offering high quality medicines at affordable prices, is paving the way in Japan as well. Together with our parent company Novartis, we are fully committed to broadening access to innovative and affordable biopharmaceuticals over the years and decades to come, both in Japan and worldwide."

The Ministry of Health, Labor and Wealth (MHLW) announced the approval on June 22, barely three months after the Japanese authorities published guidelines that paved the way for a national biosimilar regulatory pathway, based on similar scientific principles to the approval pathway already in place in the European Union.

The Sandoz product will be marketed in Japan as Somatropin BS S.C. injection 5mg / 10mg [Sandoz]. It is approved for the treatment of growth hormone deficiency in children and growth disturbance associated with Turner's syndrome or chronic renal insufficiency. This is the same range of indications covered by the reference product, Genotropin<sup>®</sup>, as approved in Japan<sup>1</sup>. It is approved on the basis that it offers patients comparable quality, safety and efficacy to the reference product.

Sandoz pioneered the field of biosimilars / follow-on biologics with the approval and subsequent launch of Omnitrope<sup>®</sup> in the US and Europe. Omnitrope was the first such product to be made available to patients in both regions and the first ever medicine to be

approved in the EU as a biosimilar, the European regulatory term for such products. Sandoz today is the only company with three biosimilar medicines marketed in Europe.

Biosimilars are an integral part of the Sandoz strategy to focus on difficult-to-make products 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 and broadening global access to medicines. Sandoz is building a strong global biosimilar pipeline, with numerous projects at all stages of development.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as “paves way for,” “paving the way,” “committed,” “will,” or similar expressions, or by express or implied discussions regarding potential marketing approvals for other biosimilar products, or regarding potential future revenues from somatropin/Omnitrope or other biosimilar 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 other biosimilar products will be submitted for approval or approved for sale in any market. Nor can there be any guarantee that somatropin/Omnitrope, or other biosimilar 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 developmental delays, including unexpected clinical or other laboratory data; unexpected regulatory actions or delays or government regulation generally; 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.

#### **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 approximately 1000 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 2008, Sandoz employed around 23,000 people worldwide and posted sales of USD 7.6 billion.

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#### **For further information**

<b>Eric Althoff</b> Novartis Global Media Relations +41 61 32 47999 eric.althoff@novartis.com	<b>Chris Lewis</b> Sandoz Global Communications +49 172 141 8749 chris.lewis@sandoz.com
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## Novartis Investor Relations

<b>International:</b> <b>Ruth Metzler-Arnold</b> Pierre-Michel Bringer John Gilardi Thomas Hungerbuehler Isabella Zinck Central phone no: +41 61 324 7944 E-mail: investor.relations@novartis.com	<b>North America:</b> Richard Jarvis +1 212 830 2433 Jill Pozarek +1 212 830 2445 Edwin Valeriano +1 212 830 2456 E-mail: investor.relations@novartis.com
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<sup>1</sup> Genotropin<sup>®</sup> is a registered trademark of Pfizer