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Sandoz receives positive EU opinion for approval of epoetin alfa biosimilar

- *European approval would provide patients suffering from low red blood cells and healthcare payors access to a high quality, cost-effective treatment*
- *Sandoz at the forefront of bringing follow-on biological medicines to patients worldwide following precedent-setting approval of Omnitrope in 2006*
- *Sandoz pipeline includes several biosimilar projects for other leading biotech medicines*

HOLZKIRCHEN (Germany), June 22, 2007 – Sandoz is the first company to receive a positive opinion from European Union regulators supporting the approval of a biosimilar version of epoetin alfa, achieving another important milestone in its efforts to bring follow-on biological medicines to patients.

More than 250,000 patients in Europe are estimated to be treated with epoetin alfa, which is marketed under various brand names, and similar medicines to regulate the formation of red blood cells. Worldwide annual sales are estimated at more than USD 7 billion, including USD 600 million in Europe.

The Committee on Medicinal Products for Human Use (CHMP), which reviews medicines scientifically in the European Union, has now for the second time issued a positive opinion for a Sandoz biosimilar. In a precedent-setting decision in April 2006, Sandoz was the first company to get European approval for such a medicine, the human growth hormone Omnitrope[®], while US approval was granted in May 2006.

The European Commission will now decide on granting approval for this biosimilar developed by Sandoz.

“The positive opinion is another important milestone for Sandoz as we lead the way to bring high-quality and cost-effective biosimilars to the market following the expiry of patents,” said Andreas Rummelt, CEO of Sandoz.

“We look forward to receiving European Commission approval for this medicine and providing patients and healthcare payors a high quality treatment that will improve access for patients and also contribute significant savings to healthcare budgets. We are committed to further developing these types of medicines and have several projects in the pipeline,” Rummelt said.

The CHMP recommendation supports the use of epoetin alfa for indications approved for the reference product at the time of the Sandoz application for EU approval. These include the use in treating patients with renal anemia as well as those receiving chemotherapy, and specifically excludes the subcutaneous administration for patients with chronic kidney disease and the use to increase the yield of autologous blood from patients in a predonation program.

Biopharmaceuticals are medicinal products manufactured by biotechnology methods. They are complex protein molecules with a high molecular weight derived from living organisms that have been genetically modified to produce the desired protein. Using advanced product development, analytical methodologies and manufacturing processes, companies like Sandoz can manufacture high quality medicines and bring them to market with savings for patients and payors.

Sandoz has been on the forefront of efforts to support the creation of regulatory review procedures to enable the approval of biosimilar medicines. Rigorous scientific criteria should be consistently applied to the approval process for these types of medicines. However, the unnecessary or unethical duplication of animal studies and human trials should be avoided, as is the case with other types of subsequent versions of medicinal products.

As more biopharmaceuticals lose patent protection in the coming years, these products are expected to play a key role in the growth strategy of Sandoz.

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 840 compounds in over 5 000 forms worldwide and sells its products in more than 110 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 drugs along with pharmaceutical and biotechnological active substances and anti-infectives. In addition to the strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany) and EonLabs (US) In 2006, Sandoz employed around 21,000 people worldwide and posted sales of USD 6 billion.

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