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Sandoz Welcomes CHMP Positive Opinion on Omnitrope

Holzkirchen, Germany, January 27, 2006 – Sandoz welcomes the positive opinion issued by the European Medicines Agency’s Committee on Medicinal Products for Human Use (CHMP) regarding the company’s recombinant human growth hormone Omnitrope.

“The positive CHMP opinion for Omnitrope is an important step on the way to make this medicine available for patients who need it,” said Dr. Andreas Rummelt, CEO Sandoz. “Omnitrope will contribute to cost savings in the Health Care systems and we are confident that the European Commission will now grant marketing authorization.”

In June 2003, the CPMP (as the Committee was named at that time) recommended that the European Commission grant Marketing Authorization for Omnitrope, but the Commission refused the Marketing Authorization on legal grounds related to the selected approval pathway. Sandoz submitted a second application in July 2004, based on a recommendation from the European Medicines Agency (EMA) and the Commission. This application followed the new Annex to Directive 2001/83/EC as amended and published with directive 2003/63/EC, which provided a pathway for these products.

Australia’s Therapeutic Goods Administration approved Omnitrope in September 2004 for treatment of growth disorders in children. The product was launched in Australia in November 2005.

In the U.S., the Food and Drug Administration notified Sandoz in August 2004, that it was unable to reach a decision on whether to approve the company’s application for Omnitrope. In September 2005, Sandoz filed a lawsuit against the US Food and Drug Administration, seeking a ruling on its pending application. That lawsuit is still pending.

“With Omnitrope’s positive status in Europe, we now hope the FDA will finally move in granting a marketing authorization for the US, acknowledging the sound science that supports this product,” said Rummelt. “We are determined to make high-quality and cost-effective biosimilar products like Omnitrope available for patients and healthcare providers worldwide.”

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, cost-efficient products that are no longer protected by patents. Sandoz has a portfolio of more than 600 active substances in over 5 000 forms worldwide. 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 (U.S.) and sells its products in more than 110 countries. In 2005, Sandoz employed around 20,000 people worldwide and posted sales of USD 4.7 billion.

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