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**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

## **Novartis receives “approvable letter” from the FDA for zoledronic acid 5 mg in the treatment of Paget’s disease of the bone**

**Basel, February 24, 2006** – Novartis announced today that it has received an “approvable letter” from the US Food and Drug Administration (FDA) for zoledronic acid (5mg infusion), which is under review for the treatment of Paget’s disease of the bone. Paget’s disease is a chronic and sometimes painful disorder affecting more than one million people in the US.

The “approvable letter” is a notification that the FDA is prepared to approve the drug and contains conditions that the applicant must meet prior to obtaining final US marketing approval. This is the second approvable letter received for zoledronic acid for this indication. In this case, the FDA has requested additional data from the ongoing clinical trial program in osteoporosis.

Novartis is confident that providing this additional information to the FDA will help obtain final approval by the end of 2006 and allow this important therapy to be offered to patients living with Paget’s disease. Submission for osteoporosis in the US and EU remains planned for 2007.

Zoledronic acid 5 mg, under the trade name Aclasta<sup>®</sup>, has been approved in 41 countries worldwide, including the EU, for the treatment of Paget’s disease.

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as “confident,” “will,” “planned,” or by express or implied discussions regarding potential regulatory approvals, potential future regulatory filings or potential future sales of zoledronic acid (5 mg infusion). Such forward-looking statements 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 any future regulatory filings will satisfy the FDA’s requirements regarding zoledronic acid, that zoledronic acid will be approved for any additional indication, that zoledronic acid (5 mg infusion) will be brought to market in the US for the treatment of Paget’s disease or any additional indication, or that the product will reach any particular level of sales. In particular, management’s expectations regarding the approval and commercialization of this product could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays, or government regulation generally; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; as well as the additional factors discussed in the Novartis AG’s Form 20-F filed 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 described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only

company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics and leading self-medication OTC brands. In 2005, the Group's businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 91,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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