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## Novartis to provide additional clarification to EU regulators on data supporting approval of Mycograb® for serious fungal infections

- *Committee for Medicinal Products for Human Use (CHMP) issues negative opinion on 2005 Mycograb submission by NeuTec, which was acquired by Novartis in mid-2006*
- *CHMP concluded that Mycograb demonstrated efficacy; negative opinion linked to questions about manufacturing and potential implications for product quality and safety*
- *Novartis to provide clarification to EU regulators to support Mycograb approval as a novel treatment for critically ill patients*

**Basel, November 17, 2006** – Novartis announced today that it plans to submit additional information to the Committee for Medicinal Products for Human Use (CHMP) in Europe to support the approval of Mycograb®, in development as a treatment for life-threatening fungal infections, after the CHMP issued a negative recommendation.

This submission for European Union approval was made in 2005 by the UK biopharmaceuticals company NeuTec Pharma, which Novartis acquired in mid-2006 to expand its portfolio of compounds for hospital-acquired fungal and bacterial infections.

The CHMP opinion was not linked to the efficacy of the compound. The Committee concluded that there was insufficient data relating to the manufacturing and characterization of the product to determine the safety of the compound. Novartis is committed to working with the CHMP to determine appropriate next steps.

Mycograb is a complex biological product produced through microbial fermentation and is produced by third party manufacturers. Novartis is working closely with these manufacturers and the CHMP to provide further clarification and analyses and is confident of gaining regulatory approval. Mycograb had not been submitted for approval in any other country.

Mycograb is a twice-daily intravenous genetically recombinant antibody fragment, or “grab,” add-on treatment targeting heat shock protein 90 (“hsp90”) developed for treatment of invasive candidiasis. This life-threatening fungal infection, which is due to the *Candida* species, has a high mortality rate.

In clinical trials, the combination of Mycograb plus amphotericin B demonstrated clear superiority over amphotericin B monotherapy, considered the standard of care. Mycograb binds to the fungal hsp90, disabling the fungal defense mechanism and making fungi more susceptible to medicines such as amphotericin B. Mycograb has been granted Orphan Drug status in Europe and the US for use against invasive fungal infections, including invasive candidiasis.

## 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, human vaccines 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 99,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

## Disclaimer

The foregoing release contains certain forward-looking statements that can be identified by terminology such as "to provide," "potential", "plans", "to expand", "committed", "confident" or similar expressions, or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Mycograb. Such forward-looking statements involve known and unknown risks, uncertainties or other factors that may cause the 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 Mycograb, or that it will ever achieve any particular level of sales. In particular, management's expectations relating to Mycograb could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including new clinical data and additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; as well as factors discussed in the Company's Form 20-F filed with the US Securities and Exchange Commission. 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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