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## Novartis announces three-month extension of US regulatory review for Galvus® to assess recently available clinical data

- *Substantial new short- and long-term data being submitted to US Food and Drug Administration (FDA)*
- *Novartis committed to working closely with the FDA to gain approval for Galvus, which has been studied in more than 7,000 people to date*

**Basel, November 13, 2006** – Novartis announced today a three-month extension in the US regulatory review period for the oral anti-diabetes medicine Galvus (vildagliptin) until the end of February 2007 after deciding to submit recently available clinical data to the US Food and Drug Administration (FDA).

These additional data being submitted to the FDA add about 1,000 patient years of treatment experience with Galvus. These recently available data include results from short- and long-term studies for periods of up to two years, both as a monotherapy or in combination with other anti-diabetes medicines.

These new data further support the proposed dosing regimen and indications as well as complement the risk/benefit profile of Galvus. In particular, they provide further evidence confirming data submitted earlier to the FDA showing that skin findings identified in a single species during a preclinical animal study have not been seen in clinical studies with patients treated for type 2 diabetes.

“We are confident of the efficacy and safety of Galvus and in gaining US approval,” said James Shannon, M.D., Head of Development at Novartis Pharma AG. “We believe this additional information being provided to the FDA will strengthen the already robust data supporting Galvus as a new and needed treatment option for patients with type 2 diabetes.”

Novartis is committed to working closely with the FDA in its review of Galvus, which the agency accepted for review in March 2006 after Novartis made the filing in January 2006. The FDA has the option of extending the typical 10-month review period for new drugs if a company submits significant additional data during the last three months of the review. An extensive clinical trial program is ongoing for Galvus.

### 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**

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