



MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

## Novartis committed to making Galvus® available for patients with type 2 diabetes after US regulators issue “approvable letter”

- *Novartis confident in safety and efficacy of Galvus as a once-daily oral treatment for patients with type 2 diabetes, over 8,000 patients in clinical trial program*
- *US Food and Drug Administration (FDA) requests additional data, including a clinical study in patients with renal impairment*
- *Discussions to continue with the FDA to obtain final US approval for Galvus*

**Basel, February 26, 2007** – Novartis announced today that it has received an “approvable letter” from the US Food and Drug Administration (FDA) for Galvus® (vildagliptin), under review for US approval as a new once-daily oral treatment for patients with type 2 diabetes.

An “approvable letter” means the FDA is prepared to approve an investigational medicine and contains conditions that must be met prior to final US approval. The FDA has requested additional data, including a clinical study to demonstrate the safety and efficacy of Galvus in specific patient groups with renal (kidney) impairment.

“We are confident in the safety and efficacy of Galvus and will continue working closely with the FDA to agree on what final actions are required to obtain US approval,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG.

The 2007 financial outlook previously communicated in January remains unchanged for the Pharmaceuticals division and for the Group.

Galvus was submitted for US approval in January 2006 as a new therapy to reduce blood sugar levels in patients with type 2 diabetes, both as a monotherapy and in use with other anti-diabetic medicines.

The global clinical trial program to date has included over 8,000 patients, with some 5,500 treated with Galvus. Submission for European Union approval was made in August 2006.

### Disclaimer

The foregoing release contains certain forward-looking statements that can be identified by terminology such as “committed,” “approvable,” “confident,” “continue,” “will continue,” “financial outlook,” or similar expressions, or by express or implied discussions regarding potential future Galvus clinical trial results, potential future approvals to market Galvus, potential future sales of Galvus, or the financial outlook of the Group and its Pharmaceuticals Division. 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 as to the results of any future clinical trials regarding Galvus, that any future regulatory filings will satisfy the FDA’s and other health authorities’ requirements regarding Galvus, that Galvus will be approved by the FDA for any indication, that Galvus will ever be brought to market in the US, the EU or any other market, or that

Galvus will reach any particular level of sales. Neither can there be any guarantee that the Group, or the Pharmaceuticals Division, will achieve any particular level of financial results. In particular, management's expectations regarding the approval and commercialization of Galvus could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, or unexpected new clinical data, including unexpected results from the clinical trials required by FDA; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; the 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.

### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure 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. 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. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 101,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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