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## **New drug application for Galvus<sup>®</sup>, an innovative oral therapy for people with type 2 diabetes, accepted for review by FDA**

- *Clinical studies show significant blood sugar reductions (HbA1c) sustained for one year*
- *Trials also show no association with weight gain; overall incidence of side effects, including hypoglycemia and edema, similar to placebo*
- *Regulatory submission includes results from more than 4,300 patients*

**EAST HANOVER, NJ, March 30, 2006** – Novartis announced today that the new drug application (NDA) for Galvus<sup>®\*</sup> (vildagliptin, formerly LAF237) was accepted for standard review by the U.S. Food and Drug Administration (FDA). If approved, Galvus will provide a new, once-daily oral treatment option for people with type 2 diabetes. Submission for approval in Europe is on track to be completed later in 2006.

Galvus, a DPP-4 inhibitor, works through a novel mechanism of action targeting the pancreatic islet dysfunction that causes high blood sugar levels in people with type 2 diabetes. Galvus affects both pancreatic alpha and beta cells, leading to a reduction in sugar production from the liver together with an increase in production of insulin needed to keep blood sugar under control.

“The prevalence of diabetes is increasing and more than half of the people who are currently taking diabetes medications are still not reaching their blood sugar goals,” said James Shannon, MD, Head of Development at Novartis Pharma AG. “Galvus may represent an exciting new option for the treatment of type 2 diabetes with the potential of helping patients reach and maintain their treatment goals with good tolerability.”

The submission includes data from clinical trials involving more than 4,300 patients worldwide evaluating the use of Galvus as monotherapy and also in combination with commonly prescribed anti-diabetic agents. Galvus is suitable for once-daily dosing. Overall, Galvus has shown clinically significant HbA1c reductions out to one year of treatment, with good overall tolerability and without causing weight gain. The most common side effects were cold-like symptoms, headache and dizziness.

“Most of the treatments that we use today focus primarily on stimulating insulin secretion or lowering resistance,” said Vivian Fonseca, MD, Professor of Medicine, Chief of Endocrinology and Metabolism, Tulane University Health Sciences Center, New Orleans, Louisiana. “The positive clinical results we’ve

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\* *The tradename Galvus<sup>®</sup> is currently pending regulatory including FDA approval.*

seen to date with Galvus underscore the importance and promise of addressing the dysfunction of both the pancreatic beta- and alpha-cells.”

### **About Galvus**

In clinical studies, Galvus has demonstrated significant reductions in blood sugar for one year. Galvus is suitable for once-daily dosing and has been evaluated both as monotherapy and in combination with other anti-diabetes agents. Galvus was not associated with overall weight gain, a key benefit for people with diabetes who struggle to keep their weight under control. The overall incidence of side effects with Galvus including hypoglycemia (excessively low blood sugar) and edema (fluid retention) was similar to placebo. Galvus lowers blood sugar by targeting islet dysfunction, i.e., it improves the ability of the islet’s alpha- and beta-cells to appropriately sense and respond to sugar in the blood.

### **About Diabetes**

Diabetes currently affects about 195 million people worldwide and is estimated to grow to more than 330 million by 2025, according to the International Diabetes Federation<sup>1</sup>. The U.S. Centers for Disease Control estimates that about 20 million Americans have diabetes.

Type 2 diabetes is a progressive disease where control of blood sugar deteriorates over time. It is the sixth leading cause of death in the U.S. and a major contributor to heart disease, stroke, blindness, kidney disease and vascular or neurological problems that can result in amputation.

Islet dysfunction and the body’s resistance to insulin both contribute to diabetes. Specifically, islet dysfunction can lead to excess sugar production (via glucagon from the alpha-cells) and reduced insulin production (from the beta-cells). Even among people receiving diabetes care, controlling blood sugar levels is difficult. More than half of those currently taking medication to manage their diabetes are still not reaching their blood sugar goals, according to data from the National Health and Nutrition Examination Survey (NHANES)<sup>2</sup>.

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as “if approved ... will provide”, “is on track to be”, “may represent”, “potential of helping” or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of vildagliptin. 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 or other health authorities’ requirements regarding vildagliptin, that vildagliptin will be approved by any health authorities for any indication, that vildagliptin will be brought to market in the US or any additional countries, or will reach any particular level of sales. In particular, management’s expectations regarding the approval and commercialization of vildagliptin could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays in 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 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 Pharmaceuticals Corporation researches, develops, manufactures and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including those in the cardiovascular, metabolic, cancer, organ transplantation, central nervous system, dermatological, gastrointestinal and respiratory areas. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG (NYSE: NVS) - 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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<sup>1</sup> <http://www.idf.org/home/index.cfm?node=37>, accessed March 9, 2006.

<sup>2</sup> Saydah SH, Fradkin J, Cowie CC. Poor Control of Risk Factors for Vascular Disease Among Adults with Previously Diagnosed Diabetes. *JAMA* 2004; 291(3):335-342.