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Galvus® receives European approval as new treatment for type 2 diabetes with broad range of indications

- *Galvus delivers robust blood sugar reductions and is well tolerated in a broad range of patients with type 2 diabetes*
- *Approved for use in combination with the most common oral anti-diabetes medicines – metformin, thiazolidinediones or sulfonylureas*
- *More than half of patients currently taking medicines to treat type 2 diabetes are still not reaching their blood sugar goals*

Basel, September 28, 2007 – Galvus® (vildagliptin), a new once-daily oral treatment for patients with type 2 diabetes, has been granted European Union approval. Galvus is the only drug in its class to offer such a broad range of indications for use in combination therapies with other anti-diabetic medicines.

This important approval for Galvus, which is a member of a new class of drugs known as DPP-4 inhibitors, comes as physicians are increasingly searching for new drugs to combine with existing medicines. The European Commission granted approval for Galvus to be used in combination with some of the most frequently prescribed oral anti-diabetes medicines – metformin, sulfonylureas (SUs) or thiazolidinediones (TZDs).

The approval applies in all 27 countries of the European Union as well as in Norway and Iceland. The International Diabetes Federation (IDF) Diabetes Atlas estimates that approximately 28 million people in developed countries have type 2 diabetes¹, and more than half of patients with this disease are still not reaching their treatment goals despite undergoing medical treatment².

“The approval of Galvus is a major milestone for the millions of type 2 diabetes patients across Europe who are being treated but still not reaching optimal blood sugar levels,” said Burkhard Göke, MD, of the Department of Gastroenterology at Ludwig-Maximilians-University in Munich, Germany.

“Galvus lowers high blood sugar levels with no weight gain and a low incidence of hypoglycemia, two side effects commonly associated with currently available drugs such as SUs and TZDs. With Galvus, we now have another treatment option to help get patients to goal,” said Dr. Göke.

Galvus delivers significant blood sugar reductions when used in combination with the most commonly used oral diabetes medicines^{3,4,5} in a range of type 2 diabetes patients. These include patients from varied ethnic groups⁶, the elderly⁷ and those with uncontrolled blood sugar levels⁸.

“We are delighted that Galvus is approved in Europe for patients with type 2 diabetes,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “Our rigorous clinical trial program has demonstrated the robust efficacy and tolerability of Galvus, which offers versatility to physicians looking for new treatment options.”

Galvus is already approved in Brazil and Mexico. In February 2007, Novartis received an “approvable letter” from the US Food and Drug Administration (FDA). Novartis has submitted a proposal to the FDA for additional clinical studies in patients with renal impairment to confirm good tolerability in this patient group.

Galvus works through a novel mechanism of action by targeting the dysfunction in the pancreatic islets that cause high blood sugar levels in people with type 2 diabetes. Islet dysfunction, along with insulin resistance, is a contributory factor of type 2 diabetes.

In clinical trials, Galvus demonstrated an overall incidence of side effects similar to placebo. The most common side effects seen in the Galvus clinical program were stuffy nose, headaches, dizziness and upper respiratory tract infection.

Diabetes is a progressive disease that is the fourth leading cause of death in most developed nations⁹. When left untreated or not kept under control, type 2 diabetes can lead to heart and kidney disease, blindness and vascular or neurological problems⁹.

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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 more than

100,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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