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## **Eucreas<sup>®</sup>, a single-tablet combination of Galvus<sup>®</sup> and metformin, set for launch in first EU countries as new treatment for type 2 diabetes**

- *Patients uncontrolled on metformin four times more likely to achieve blood sugar control on Eucreas compared to placebo*
- *First single-tablet combination of a DPP-4 inhibitor and metformin approved for European countries*
- *Eucreas results in no overall weight gain and low incidence of hypoglycemia*
- *Both Eucreas and Galvus to be available to patients in the first EU countries in the next few weeks*

**Basel, February 25, 2008** – European health authorities have approved Eucreas<sup>®</sup>, an oral tablet combining Galvus<sup>®</sup> (vildagliptin) and metformin, as a new treatment for patients with type 2 diabetes. Eucreas is the first single-tablet combination of a member of the new DPP-4 inhibitor class with metformin to be approved in the European Union.

The approval comes after Novartis proposed changes to the EU label recommending that liver monitoring should be conducted at the start of treatment, every three months for the first year, and periodically thereafter. The Eucreas approval closely follows European approval of the updated label for Galvus announced earlier this month.

The decision applies in all 27 countries of the EU as well as in Norway and Iceland, and both medicines will be available in the first European countries within the next few weeks.

Studies show that more than half of patients currently taking medication to manage their type 2 diabetes are still not reaching blood glucose goals<sup>1</sup>. Combination therapy usually becomes necessary due to progressive worsening of blood sugar control during the natural course of the disease<sup>2</sup>.

In clinical studies, patients inadequately controlled on metformin, one of the most prescribed oral therapies for type 2 diabetes, were four times more likely to achieve blood sugar control by adding Galvus to their treatment compared to those who added a placebo (or sugar pill)<sup>3</sup>. Furthermore, Galvus when administered with metformin resulted in additional blood sugar reductions of 1.1% as measured by HbA1c<sup>4</sup>, the gold standard measure of blood sugar control<sup>5</sup>.

“The approval of Eucreas marks an important step forward in the management of type 2 diabetes, as it is the first single-tablet combination of a DPP-4 inhibitor with metformin for patients in Europe,” said James Shannon, MD, Chief Medical Officer at Novartis Pharma AG. “The complementary actions of Galvus and metformin, which are the medicines

combined in Eucreas, help to bring blood sugar levels under control without the side effects commonly associated with many widely-used type 2 diabetes medicines.”

In clinical trials, the addition of Galvus to metformin provided robust blood sugar control without weight gain and with fewer cases of hypoglycemia (i.e. dangerously low blood sugar)<sup>4</sup>, side effects associated with other therapies for type 2 diabetes such as sulfonylureas or thiazolidinediones.

Eucreas has been approved for use in type 2 diabetes patients who are inadequately controlled with metformin alone, or are being treated with Galvus and metformin as separate tablets. Eucreas is recommended for use twice-daily at a dose of either 50 mg vildagliptin/850 mg metformin or 50 mg vildagliptin/1000 mg metformin.

Eucreas combines two agents that work together to target both a dysfunction in the pancreatic islets and insulin resistance, two of the main factors contributing to type 2 diabetes. Galvus works through a novel mechanism of action that targets islet dysfunction and restores the body’s natural ability to increase insulin and decrease glucagon – the two main hormones controlling blood sugar levels. Metformin works mainly by decreasing the production of sugar by the liver and increasing insulin sensitivity.

Type 2 diabetes is a progressive disease in which control of blood sugar deteriorates over time. If left untreated or not kept under control, it can lead to heart and kidney disease, blindness, and vascular or neurological problems<sup>6</sup>.

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The foregoing release contains forward-looking statements that can be identified by terminology such as “likely,” “to be,” “will,” “usually,” “can” or similar expressions, or by express or implied discussions regarding the launch of Galvus and Eucreas in Europe, potential future approvals of Galvus and Eucreas in other countries, potential new indications or labelling for Galvus and Eucreas or regarding potential future revenues from Galvus and Eucreas. Such forward-looking statements reflect the current views of Novartis regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Galvus and Eucreas to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Galvus and Eucreas will be approved for sale, or for any additional indications or labelling in any market. Nor can there be any guarantee that Galvus and Eucreas will be launched in any particular market, or will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Galvus and Eucreas could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; production delays or business interruption generally; government, industry and general public pricing pressures, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the U.S. 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 anticipated, believed, estimated or expected. 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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