

## New evidence reinforces efficacy and tolerability of Galvus® as a new once-daily oral treatment option for patients with type 2 diabetes

- *New clinical data demonstrate improved blood glucose control with excellent safety profile in elderly patients with type 2 diabetes*
- *Pooled results confirm efficacy of once-daily dosing with Galvus monotherapy*
- *Galvus improves islet cell dysfunction, one of the core defects that contributes to the progression of type 2 diabetes*

**Basel, December 6, 2006** – New data show that Galvus® (vildagliptin), an investigational once-daily oral medicine for patients with type 2 diabetes, significantly reduced blood sugar levels in people age 65 and older – a growing group of patients with this progressive disease who can be difficult to treat with existing oral therapies<sup>1</sup>.

Pooled analyses from a number of Phase III studies showed significant improvements in blood sugar control among patients in this age group when treated with Galvus without the increased risk of side effects that often limits more aggressive treatment in these patients<sup>1</sup>.

The findings were included among the 12 Galvus abstracts featured at this week's 19<sup>th</sup> World Diabetes Congress of the International Diabetes Federation (IDF) in Cape Town, South Africa.

The efficacy of once-daily dosing for Galvus monotherapy was also highlighted at the congress. Data from a number of Phase III monotherapy trials lasting from 12 to 52 weeks in patients taking 100 mg of Galvus daily showed overall blood sugar reductions of 1% in A1C (an average blood sugar measure over two to three months) and up to 1.8% in those with the highest baseline blood sugar levels<sup>2</sup>.

Other new results presented at the congress demonstrated how Galvus improved overall islet cell function, with a decline in islet cell function being one of the core factors contributing to the progression of type 2 diabetes. Galvus works by suppressing excessive glucagon secretion by the alpha cells<sup>3</sup> and stimulating insulin secretion by the beta cells<sup>4</sup>. Both of these effects contribute to the glucose lowering efficacy of Galvus.

“These data confirm Galvus effectively reduces blood sugar levels and has a positive effect on pancreatic islet cell function,” said Vivian Fonseca, MD, Professor of Medicine and Chief of Endocrinology and Metabolism at Tulane University Health Sciences Center in New Orleans, Louisiana.

“Clinical trials show that Galvus may help a broad range of patients reach treatment goals, even older patients who are often difficult to treat. The data also show the potential of Galvus to modify the natural course of type 2 diabetes,” Dr. Fonseca said.

More on the Galvus studies at IDF

Researchers who reviewed data from two Phase III trials involving more than 500 patients with type 2 diabetes found that the study data reflected Galvus' potential as an effective monotherapy in patients aged 65 and older. Treatment with Galvus resulted in similar reductions in A1C among patients aged above and below 65, with drops of up to 1.1%<sup>1</sup>.

A separate analysis of 2,000 patients of all ages with type 2 diabetes across eight monotherapy trials indicated that Galvus is extremely well tolerated in patients aged 65 and above, with a very low incidence of hypoglycemia or low blood sugar – a particular concern in older patients with type 2 diabetes<sup>1</sup>.

More than 25% of all patients over age 60 are estimated to have type 2 diabetes<sup>5</sup>, but the condition is often undiagnosed and treatment options in older patients remain inadequate<sup>6</sup>.

Pooled data from four trials in a broader type 2 diabetes population (about 40 to 65 years old) confirmed previous findings that there was no overall weight gain in those using once-daily Galvus monotherapy<sup>7</sup>. This is a key benefit for many patients with type 2 diabetes who often struggle to keep their weight under control.

“The clinical profile of Galvus has been well established by our deep and robust clinical trial program,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “As the most widely studied DPP-4 inhibitor to date, we have demonstrated that Galvus can be an effective treatment for a broad range of patients with type 2 diabetes – including those who have unique treatment challenges and needs – without the overall weight gain and many side effects associated with other treatments.”

#### About diabetes

Type 2 (also known as adult-onset) diabetes is a progressive disease where control of blood glucose deteriorates over time. The two contributing factors are dysfunction of the islet cells of the pancreas and resistance by the body's cells to circulating insulin. Two important cells in the pancreas are the alpha cells, which secrete a hormone called glucagon, and the beta cells which secrete insulin.

In a healthy individual these two hormones work together to maintain normal blood glucose levels. In patients with type 2 diabetes, there is too much glucagon stimulating blood glucose production, and too little insulin promoting its uptake by the body. Furthermore, islet function deteriorates over time and is one of the key drivers for the progression of type 2 diabetes.

Even among patients receiving diabetes care, controlling blood sugar levels is still difficult. More than half of patients with type 2 diabetes currently taking medicines are still not reaching their blood sugar goals, according to the National Health and Nutrition Examination Survey (NHANES)<sup>8</sup>.

If type 2 diabetes is left untreated or not under control, it can lead to heart and kidney disease, blindness, and vascular or neurological problems. In most developed nations, diabetes is the fourth leading cause of death. Recently published statistics from the International Diabetes Federation's Diabetes Atlas show that diabetes now affects 246 million people worldwide. The new data predict that the total number of people living with diabetes will increase to 380 million within twenty years<sup>9</sup>.

#### About Galvus

Galvus works through a novel mechanism of action by targeting the pancreatic islet dysfunction that causes high blood sugar levels in patients with type 2 diabetes. Specifically, islet dysfunction can lead to excess sugar production (via glucagon from the alpha cells) and reduced insulin production (from the beta cells).

In clinical studies, Galvus has demonstrated significant reductions in blood sugar sustained at two years. Galvus is suitable for once-daily dosing and has been evaluated both as monotherapy and in combination with other anti-diabetes agents. Galvus also improved the ability of the pancreatic alpha and beta cells to appropriately sense and respond to sugar in the blood.

The overall incidence of side effects with Galvus, including hypoglycemia (excessively low blood sugar) and edema (fluid retention), was similar to placebo in monotherapy trials. The most common side effects seen in the Galvus clinical program were cold/flu-like symptoms, headaches and dizziness.

A US regulatory decision is expected in the first half of 2007 for Galvus as a once-daily oral treatment for patients with type 2 diabetes. The US Food and Drug Administration (FDA) extended the review period for Galvus by three months from November 2006 after recently available clinical data were submitted to support the proposed dosing and indications as well as complement earlier data on the risk/benefit profile. The additional data being submitted add around 1,000 patient-years of treatment experience with Galvus and include results from short- and long-term studies for periods of up to two years, both as a monotherapy and in combination with other anti-diabetes medicines. The European marketing application for Galvus was filed in August 2006.

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#### References

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