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## **New data from multiple studies show Galvus® delivers consistent and robust blood sugar control in patients with type 2 diabetes**

- *Significant blood sugar reductions seen across range of patient populations, including varied ethnic groups, the elderly, and those at high risk of developing diabetes*
- *Galvus lowers blood sugar when added to a sulfonylurea, reinforcing efficacy in combination with commonly used diabetes medicines*
- *Data confirm good tolerability in humans with studies showing incidence of side effects similar to placebo in monotherapy trials*
- *European regulatory decision anticipated by end 2007; discussions continue on steps to gain US approval*

**Basel, June 25, 2007** – Galvus® (vildagliptin), a new once-daily oral treatment for type 2 diabetes submitted for approval in the US and Europe, has been shown in new clinical data to deliver consistent and robust blood sugar reductions in patients with this progressive disease estimated to affect about 246 million people worldwide<sup>1</sup>.

The findings, presented at the 67th Annual Scientific Sessions of the American Diabetes Association (ADA), are consistent with earlier results demonstrating the efficacy and tolerability of Galvus both as a monotherapy and when added to many commonly used diabetes medicines in a range of patients across the type 2 diabetes disease spectrum<sup>2,3,4</sup>. These include varied ethnic groups<sup>3</sup> and the elderly<sup>4</sup> as well as patients with impaired glucose tolerance at high risk of developing diabetes<sup>5</sup> and those with uncontrolled blood sugar levels<sup>6</sup>.

“These results further reinforce the clinical benefits of Galvus as an important new treatment option for patients with type 2 diabetes,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “We remain convinced that Galvus is safe and effective and will continue to work with health authorities to ensure this medicine can be made available to patients worldwide as soon as possible.”

A member of a new class of diabetes medicines called DPP-4 inhibitors, Galvus is currently approved in Brazil and Mexico. A European regulatory decision is anticipated by the end of 2007. In the US, Novartis received an approvable letter in February 2007, and discussions are ongoing with the US Food and Drug Administration on steps needed to move forward to approval.

New data presented at the ADA showed that Galvus, when added to the sulfonylurea glimepiride, produced an additional significant blood sugar reduction of 0.6% in HbA1c compared to glimepiride alone<sup>2</sup>. HbA1c is a measure of plasma glucose levels over the preceding three months, and indicates how well diabetes is being controlled over time.

These data supplement existing findings with Galvus when used in combination with widely prescribed diabetes medicines such as metformin, an oral thiazolidinedione (TZD) and insulin.

In the Galvus clinical program no evidence has been seen of overall weight gain<sup>7</sup> or hypoglycemia (dangerously low blood sugar levels)<sup>8</sup>, side effects commonly associated with some type 2 diabetes medications. The overall incidence of side effects, including edema (fluid retention), was similar to placebo in monotherapy trials<sup>8</sup>.

“Taken together, these data provide evidence that vildagliptin could provide a safe, effective and well-tolerated therapy when used alone or in combination with other anti-diabetic therapies,” said Alan J. Garber, MD, Ph.D, Professor of Medicine, Biochemistry and Molecular Biology, and Molecular and Cellular Biology at the Baylor College of Medicine in Houston, Texas. “The majority of patients with type 2 diabetes have not achieved their A1c goals and it may therefore be helpful to have additional therapeutic options such as vildagliptin.”

In most developed nations, diabetes is the fourth leading cause of death<sup>9</sup>. Controlling blood sugar levels is difficult even among patients receiving treatment, and more than half of patients with type 2 diabetes currently taking medicines are still not reaching their blood sugar goals<sup>10</sup>. When left untreated or not kept under control, type 2 diabetes can lead to heart and kidney disease, blindness, and vascular or neurological problems<sup>1</sup>.

Galvus works through a novel mechanism of action, targeting a dysfunction in the pancreatic islets that causes high blood sugar levels in people with type 2 diabetes. In clinical studies, Galvus has demonstrated significant reductions in blood sugar sustained at two years<sup>8</sup>.

At a special ceremony during the congress, Novartis presented its 9th annual Novartis Prize in Diabetes to recognize five recipients for innovative patient-oriented diabetes research. For more information about the Novartis Prize in Diabetes, please visit [www.diabetesaward.novartis.com](http://www.diabetesaward.novartis.com).

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## References

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