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## **New data for Galvus® provide further evidence of robust efficacy and tolerability in treating patients with type 2 diabetes**

- *Patients uncontrolled on metformin four times more likely to achieve blood sugar control by adding Galvus to treatment regimen compared to placebo*
- *Other new data show Galvus well tolerated in patients with mild renal impairment – occurs in about one-third of all type 2 diabetes patients*
- *Galvus demonstrates robust efficacy and well tolerated in the elderly – the fastest growing group of type 2 diabetes patients*

Basel, September 17, 2007 – Uncontrolled patients with type 2 diabetes treated with metformin, one of the most prescribed oral medicines for this disease, were four times more likely to achieve recommended blood sugar control levels by adding Galvus® (vildagliptin) to their treatment compared to those who added a placebo, according to new clinical data<sup>1</sup>.

The study of 544 patients with type 2 diabetes who were inadequately controlled on metformin showed that 35.5% achieved glycemic control (HbA1c < 7.0%) when Galvus was added to the treatment regimen with metformin compared to 9.4% of those receiving metformin along with placebo (or sugar pill)<sup>1</sup>.

The results further showed that 54.1% of patients in a subset group with a baseline HbA1c of less than 8.0% achieved glycemic control after taking both Galvus and metformin compared to 13.3% among those who received metformin and a placebo<sup>1</sup>.

HbA1c is a test done to measure the average amount of sugar in the blood over the last two to three months. The American Diabetes Association recommends an HbA1c level of less than 7.0% to minimize the risk of severe complications, which can include heart disease, blindness, amputations, nerve damage and kidney failure<sup>2</sup>.

These findings, presented at the 43<sup>rd</sup> European Association for the Study of Diabetes (EASD), add to the growing evidence of data demonstrating the efficacy and tolerability of Galvus in treating a wide range of patients with type 2 diabetes, a progressive disease estimated to affect more than 28 million people in the European Union<sup>3</sup>.

Galvus is a member of a new class of medicines called DPP-4 inhibitors. European Union approval is expected soon after the Committee for Medicinal Products for Human Use (CHMP), which reviews medicines scientifically in Europe, issued a positive opinion in July 2007. Galvus is expected to be approved as an add-on therapy to the most common oral anti-diabetes medicines – metformin, thiazolidinediones, and sulfonylureas.

“Clinical trials have consistently demonstrated the robust efficacy and good tolerability of Galvus in combination with many oral diabetes therapies,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG.

“Galvus has further proven its benefits in a wide range of patients, helping to bring blood sugar levels under control without the side effects, including weight gain and hypoglycemia, associated with other type 2 diabetes medicines such as sulfonylureas or thiazolidinediones,” Dr. Shannon said.

Other data presented at the meeting confirmed that Galvus is well tolerated in patients with mild renal impairment<sup>4</sup>, a condition seen in about one-third of all type 2 diabetes patients<sup>5</sup>. Galvus also delivers strong efficacy and tolerability in the elderly<sup>6</sup>, the fastest growing group of type 2 diabetes patients<sup>7</sup>.

Separately, a new analysis of pooled data from 1,864 patients showed the safety and tolerability of Galvus in patients with predominantly mild renal (kidney) impairment was similar to both placebo as well as to patients who did not have renal impairment<sup>4</sup>. Type 2 diabetes is seen in some countries as the most frequent condition in people with renal impairment<sup>5</sup>. Almost half of all patients treated with Galvus during the clinical trial program had renal impairment.

Other data presented at the meeting included a pooled analysis of five monotherapy studies demonstrating the efficacy and safety of Galvus in the elderly. This group of 238 patients were all over age 65 and had a mean age of 70. Galvus provided significant blood sugar reductions of 1.2% as measured by HbA1c, was well tolerated and associated with a low risk of hypoglycemia<sup>6</sup>. Elderly patients can be difficult to treat with existing oral therapies<sup>7</sup>.

“It is important to have new treatment options that are both effective and well tolerated to address the growing number of elderly patients who have type 2 diabetes,” said Richard Pratley, MD, Director of Diabetes & Metabolism Translational Medicine at the University of Vermont. “Clinical data have continually demonstrated that vildagliptin, when added to metformin, sulfonylureas, thiazolidinediones or when used alone, effectively reduces blood sugar levels and is well tolerated in a range of patients.”

Galvus is currently available 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. The submission of additional data to the FDA is expected in 2009.

Galvus works through a novel mechanism of action by targeting the dysfunction in the pancreatic islets that causes high blood sugar levels in people with type 2 diabetes. Islet dysfunction, along with insulin resistance, is a contributory factor in type 2 diabetes. The most frequent side effects seen in the Galvus clinical program were stuffy nose, headaches, dizziness and upper respiratory tract infection.

In most developed nations, diabetes is the fourth leading cause of death<sup>7</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>8</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>7</sup>.

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## **Novartis Media Relations**

### **John Gilardi**

Novartis Global Media Relations  
+41 61 324 3018 (direct)  
+41 79 596 14008 (mobile)  
john.gilardi@novartis.com

### **Navjot Rai**

Novartis Pharma Communications  
+41 61 324 6498 (direct)  
+41 79 777 6400 (mobile)  
navjot.rai@novartis.com

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

## **Novartis Investor Relations**

### **International**

**Ruth Metzler-Arnold**  
Katharina Ambuehl  
Nafida Bendali  
Pierre-Michel Bringer  
Jason Hannon  
Thomas Hungerbuehler  
Richard Jarvis

### **North America**

<b>Ronen Tamir</b>	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

Central phone no: +41 61 324 7944

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)