NOVARTIS AG
Form 6-K
June 14, 2006

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER**

**PURSUANT TO RULE 13a-16 or 15d-16 OF**

**THE SECURITIES EXCHANGE ACT OF 1934**

**Report on Form 6-K dated June 13, 2006**

**(Commission File No.** 1-15024)

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# Novartis AG

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## Investor Relations Release

**Novartis unveils further impressive efficacy data for the investigational oral diabetes compound Galvus® showing significant blood sugar reductions**

- ***New data show blood sugar (HbA1c) reduction of up to 2.8% with the combination of Galvus and pioglitazone in type 2 diabetic patients with poor glycemic control***

- ***Data also show no significant additional weight gain and less edema (fluid retention) compared to pioglitazone alone***

- ***Mean weight loss in obese patients observed in a separate head-to-head study vs. rosiglitazone with comparable reductions in HbA1c***

- ***Overall Phase III program confirms once-daily dosing and efficacy comparable to TZDs, both as monotherapy and in combination with other anti-diabetic agents***

- ***Novartis announces GLORIOUS mega-trials program to evaluate impact of Galvus on progression of type 2 diabetes and patient outcomes***

**Basel, June 13, 2006** Galvus®* (vildagliptin), seeking to become a new once-daily oral treatment option for type 2 diabetes, has demonstrated impressive efficacy, especially in patients with poor glycemic control, as well as weight loss benefits in obese patients.

These new findings from Phase III studies were presented today at a late-breaker session at the 66th Scientific Sessions of the American Diabetes Association (ADA) meeting in Washington, DC.

The combination of Galvus, a member of the DPP-4 inhibitor class, and pioglitazone led to an overall 1.9% reduction in HbA1c (a measure of blood sugar control also known as A1c). Pioglitazone is an insulin sensitizer known as a thiazolidinedione, or TZD. Two-thirds of people (65%) on Galvus and pioglitazone achieved the ADA-defined A1c goal of less than or equal to 7% versus 42% of those who achieved this goal on monotherapy (Galvus 42.5%, pioglitazone 42.9%).

More importantly, a reduction of up to 2.8% in A1c was seen among patients with poor glycemic control who had the highest mean baseline blood sugar levels (about 10%) as measured by A1c.

Also in this study, patients over age 65 who were given Galvus and pioglitazone showed an A1c drop of 2.3% from a mean A1c baseline of 8.4%. In obese patients, with a Body Mass Index (BMI) equal to or over 35, patients given Galvus and pioglitazone showed a decline of 2.2% from a mean A1c baseline of 8.6%.

* The tradename Galvus® is currently pending regulatory, including FDA, approval

2

In a separate head-to-head comparison with rosiglitazone, another insulin sensitizer, Galvus demonstrated comparable efficacy. Among severely obese Galvus-treated patients, there was a mean reduction of body weight greater than 1 kg, with an overall mean difference of 2.8 kg between the Galvus and rosiglitazone treatment groups.

These new data underscore the significant efficacy and good tolerability that have been consistently observed in the robust Galvus clinical development program, said James Shannon, MD, Head of Development at Novartis Pharma AG.

The magnitude of A1c reductions seen in the combination of Galvus and a TZD is encouraging for patients struggling to reach and maintain their blood sugar levels. The trial results for Galvus continue to reinforce the benefits of treating both islet dysfunction and insulin resistance in type 2 diabetes, Shannon said.

Throughout the Phase III program, Galvus has shown clinically significant and consistent A1c reductions both as monotherapy and in combination with other oral and injectable anti-diabetic agents. Galvus has demonstrated a good tolerability profile in these studies, with no weight gain overall and an incidence of hypoglycemia (excessively low blood sugar) and edema (fluid retention) similar to placebo in monotherapy trials.

As the diabetes epidemic continues to grow worldwide, there is a very real and urgent need for new ways to help control blood sugar levels in people with type 2 diabetes, said Julio Rosenstock, MD, Director of Dallas Diabetes and Endocrine Center at Medical City, Clinical Professor of Medicine, University of Texas, Southwestern Medical School Dallas, Texas and a lead investigator in the Galvus/pioglitazone trial. We were pleased to see the especially steep reductions of glucose in the subanalysis of patients with the highest blood sugar levels. However, this high baseline population represents a difficult to treat group and these patients usually require a multi-drug strategy to reach glycemic goal.

Galvus was accepted for US regulatory review earlier in 2006. The submission includes data from clinical trials involving more than 4,300 patients worldwide. Regulatory filings in the EU are planned to be completed later in 2006.

**About the trials**

The two trials were highlighted at the ADA late-breaker session as part of a broad overview of clinical data summarizing the development as well as overall efficacy and tolerability of Galvus.

The first was a six-month clinical trial evaluating the combination of Galvus and pioglitazone (Pio) in patients with type 2 diabetes. The study evaluated 592 patients who had never been previously treated for type 2 diabetes and who had a baseline A1c of between 7.5% and 11%. It involved four treatment groups: (1) Galvus 100 mg; (2) Pio 30 mg; (3) Galvus 100 mg + Pio 30 mg; (4) Galvus 50 mg + Pio 15 mg.

Among patients with baseline A1c of 9% or greater, the combination of Galvus and Pio produced a 2.8% reduction in A1c. In the overall population, patients receiving Galvus 100 mg + Pio 30 mg saw a statistically significant overall reduction in A1c compared to those on Pio alone (1.9% vs. 1.4%, $p < 0.001$).

Adverse events were consistent with the individual safety profiles of Galvus and TZDs. The patients treated with the combination of Galvus and Pio experienced no significant additional weight gain and less edema (fluid retention) compared to patients taking Pio alone.

The second trial involved 700 patients in a six-month head-to-head comparison of Galvus (100 mg daily) and rosiglitazone (8 mg once/day). Galvus reduced blood sugar levels significantly (-1.1%) as measured by A1c, with no difference between treatment groups. Galvus treatment was not associated with weight gain overall, while people in the rosiglitazone group gained on average 1.6 kg. Galvus-treated patients also experienced a lower incidence of edema (2.5% vs. 4.9%).

The initial results from this trial were presented at an ADA poster session at 10:00 am EDT on Saturday, June 10 (abstract 557-P).

In an additional subgroup analysis of severely obese patients presented at the late-breaker session, there was a mean reduction of body weight greater than 1 kg in the Galvus group, with a mean difference between the Galvus and rosiglitazone groups of 2.8 kg.

**About the GLORIOUS mega-trial program**

Novartis is committed to developing therapies that will impact the progression of type 2 diabetes. This was confirmed through the announcement at the ADA meeting of the GLORIOUS mega-trial program, one of the largest series of outcomes-focused clinical programs conducted among people with type 2 diabetes. Novartis intends to provide additional details on the program later in 2006.

**About Galvus**

Galvus, a member of the DPP-4 inhibitor class, works through a novel mechanism of action targeting the pancreatic islet dysfunction that causes high blood sugar levels in people 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). Galvus affects both pancreatic alpha and beta cells, improving their ability to appropriately sense and respond to sugar in the blood.

In clinical studies, Galvus has demonstrated significant reductions in blood sugar sustained at one year. Galvus is suitable for once-daily dosing and has been evaluated both as monotherapy and in combination with other anti-diabetes agents. Galvus is not associated with weight gain overall, a key benefit for people with diabetes who struggle to keep their weight under control. 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.

**About diabetes**

Diabetes currently affects about 195 million people worldwide and is estimated to grow to more than 330 million by 2025, according to the International Diabetes Federation. While the disease burden among Western nations is great, the IDF projects a 170% increase in type 2 diabetes cases in the developing world by 2025.1

Type 2 diabetes is a progressive disease where blood sugar control deteriorates over time.2 Diabetes 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.1

Islet dysfunction and the body s resistance to insulin both contribute to diabetes. Even among people receiving diabetes care, controlling blood sugar levels is difficult. More than half of those currently taking medicines to manage their diabetes are still not reaching their blood sugar goals, according to data from the National Health and Nutrition Examination Survey (NHANES).3

**Disclaimer**

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as to evaluate , seeking to become , encouraging , continue to , planned , committed or similar expressions, or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Galvus. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Galvus will be approved for sale in any market, or that Galvus will reach any particular level of sales. In particular, management s expectations regarding the approval and commercialization of Galvus could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; unexpected regulatory actions or delays in government regulation generally; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; as well as the additional factors discussed in Novartis AG s Form 20-F filed with the US 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 described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

**About Novartis**

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat 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. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. 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. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 96,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

**References**

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Novartis AG**

Date: June 13, 2006

By: /s/ MALCOLM B. CHEETHAM
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