

NOVARTIS AG  
Form 6-K  
September 18, 2007

# 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 September 17, 2007

(Commission File No. 1-15024)

### Novartis AG

(Name of Registrant)

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4056 Basel

Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F:  Form 40-F:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

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Yes:  No:

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes:  No:



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**- Investor Relations Release -**

**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(1).

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)(1).

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(1).

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(2).

These findings, presented at the 43rd 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(3).

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(4), a condition seen in about one-third of all type 2 diabetes patients(5). Galvus also delivers strong efficacy and tolerability in the elderly(6), the fastest growing group of type 2 diabetes patients(7).

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(4). Type 2 diabetes is seen in some countries as the most frequent condition in people with renal impairment(5). 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(6). Elderly patients can be difficult to treat with existing oral therapies(7).

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(7). 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(8). When left

untreated or not kept under control, type 2 diabetes can lead to heart and kidney disease, blindness and vascular or neurological problems(7).

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as more likely, can, expected, or similar expressions, or by express or implied discussions regarding potential regulatory approvals for Galvus or regarding potential future revenues from Galvus. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Galvus 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 the US, in the EU, or in any other market. Nor can there be any guarantee that Galvus will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Galvus 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; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; and other risks and factors referred to in Novartis AG's current Form 20-F on file 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 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.

#### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure 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. 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. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ more than 100,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

#### **References**

- (1) Dejager S, et al. Achievement of Glycemic Targets with Vildagliptin. Presented at EASD 17-21 September 2007 (Abstract A-07-899).
- (2) American Diabetes Association. Diabetes and Cardiovascular (Heart) Disease. <http://www.diabetes.org/diabetes-statistics/heart-disease.jsp>
- (3) International Diabetes Federation (IDF) Diabetes Atlas estimates there are 31 million people with diabetes in the European Union. The IDF estimates that in developed nations, 85-95% of all cases of diabetes are type 2 diabetes. 90% of those with diabetes equates to 28 million with type 2 diabetes in the European Union.
- (4) Thuren T, et al. Vildagliptin is Safe and Well Tolerated in Patients with Mild or Moderate Renal Impairment. Presented at EASD 17-21 September 2007 (Abstract A-07-1190).
- (5) International Diabetes Federation. Fact sheet Diabetes and kidney disease. 2007
- (6) Pratley R, et al. Efficacy and Safety of Vildagliptin in the Elderly: Pooled Analysis of 5 Monotherapy Studies. Presented at EASD 17-21 September 2007 (Abstract A-07-917).
- (7) International Diabetes Federation. Diabetes Atlas Third Edition. 2006.
- (8) Saydah S, et al. Poor Control of Risk Factors for Vascular Disease Among Adults with Previously Diagnosed Diabetes. JAMA 2004; 291(3):335-342.

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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: September 17, 2007

By: /s/ Malcolm B. Cheetham

Name: Malcolm B. Cheetham  
Title: Head Group Financial  
Reporting and Accounting