

NOVARTIS AG  
Form 6-K  
October 13, 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 October 12, 2006

(Commission File No. 1-15024)

**Novartis AG**

(Name of Registrant)

Lichtstrasse 35  
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:  x

Form 40-F:  o

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:  o

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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:  o

No:  x



**Novartis International AG**

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**- Investor Relations Release -**

**Novartis launches GALIANT study comparing the investigational drug Galvus® and a leading class of oral anti-diabetic medicines**

- ***Significant clinical trial designed to demonstrate that once-daily Galvus as effective as a TZD in improving blood sugar control in a primary care setting***
- ***Large-scale trial in the US illustrates ongoing commitment to study potential of Galvus in modifying treatment standards for type 2 diabetes***

**Basel, October 11, 2006** Novartis announced today the start of GALIANT, a significant clinical trial set to involve more than 7,500 people in the United States comparing the investigational oral type 2 diabetes medication Galvus® (vildagliptin) with commonly prescribed anti-diabetic oral medicines called thiazolidinediones (TZDs).

Clinical trials to date have demonstrated that treatment with Galvus results in consistent, significant and sustained reductions in blood sugar levels, leading to improved glucose control. The need for new therapies is urgent given that diabetes currently affects about 230 million people worldwide and is estimated to grow to more than 350 million by 2025, according to the International Diabetes Federation(1).

GALIANT is a three-month multi-center trial that plans to enroll more than 7,500 patients at 800 research centers throughout the US. The study will be conducted in a real world setting involving predominantly primary care physicians.

The GALIANT study is expected to build on trial results presented earlier this year that showed patients receiving Galvus as monotherapy experienced similar and significant reductions in blood sugar levels to those treated with the TZD rosiglitazone(2),(3).

Doctors across the country and the world are caring for more and more people with poorly controlled type 2 diabetes, said Richard E Pratley, MD, Professor of Medicine, Director, Diabetes & Metabolism Translational Medicine Unit, University of Vermont and a principal investigator of the GALIANT study.

There is a great need to get people to their target blood sugar. To do this, we need effective treatments that don't increase the risk for hypoglycaemia or low blood sugar. The GALIANT trial, with its focus on the primary care setting, will provide us with a full range of results that can be applied to many different types of people with diabetes and help determine the potential role the DPP-4 inhibitor, Galvus, may play in the treatment of type 2 diabetes, Dr. Pratley said.

### **About GALIANT**

The GALIANT study, which is a three-month multi-center, randomized, open-label, active-controlled trial, will compare the efficacy and safety of Galvus (100 mg once-daily) directly against insulin sensitizers, also known as TZDs, in people with type 2 diabetes already receiving metformin, but not at their target blood sugar goals. Importantly, this study will also assess the impact of Galvus on many different patient populations, including the elderly, different ethnic groups, and patients with varying degrees of body mass index (BMI).

The GALIANT trial is yet another illustration of the robust development program that supports Galvus, and our commitment to innovative research that began when Novartis pioneered the investigation of DPP-4 inhibition as a diabetes treatment target, said James Shannon, MD, Head of Development at Novartis Pharma AG. With the prevalence of type 2 diabetes escalating in countries around the globe, Novartis is fully committed to and engaged with the world's leading diabetes physicians and researchers who are dedicated to improving treatment options for people with type 2 diabetes.

### **About Galvus**

Galvus 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).

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 also improved the pancreatic alpha and beta cells' ability to appropriately sense and respond to sugar in the blood. Galvus is not associated with weight gain in the overall patient population, 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.

Both the US Food and Drug Administration and European Union regulatory agencies are reviewing applications seeking approval of Galvus to treat patients with type 2 diabetes. Regulatory action from the FDA is expected by the end of 2006.

### **About diabetes**

Type 2 diabetes is a progressive disease where blood sugar control deteriorates over time(4). 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).

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).

Islet dysfunction and the body's resistance to insulin both contribute to the development of 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)(5).

### **Novartis commitment to the treatment of diabetes**

More than 7,000 patients have participated in the Galvus clinical development program to date with approximately 4,500 having been treated with Galvus. The robust Novartis clinical development program for Galvus continues to expand with more than 60 studies completed or underway.

Novartis has also recently announced the start 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 in the next few months.

### **Disclaimer**

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as launches, designed to, commitment to, potential, start, set to, estimated to, plans to, will, expected, may, committed, or similar expressions, or by express or implied discussions regarding potential future regulatory approvals or potential 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 regulatory actions or delays, or government regulation generally; competition in general; unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 97,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

### **References**

- (1) <http://www.idf.org/home/index.cfm?node=37>, accessed October 6, 2006.
- (2) Rosenstock J, Baron M, Schweizer A, et al. Vildagliptin is as effective as rosiglitazone in lowering HbA1c but without weight gain in drug-naive patients with type 2 diabetes (T2DM). Presented at ADA, June 11, 2006; Washington, DC. [http://www.ndei.org/v2/website/content/index.cfm?MiscContent\\_ID=655](http://www.ndei.org/v2/website/content/index.cfm?MiscContent_ID=655)

- (3) A. Schweizer, S. Dejager, M.A. Baron, D. Mills, Y. Amiour, J. Rosenstock. Vildagliptin is as Effective as Rosiglitazone in Drug-Naïve Patients with Type 2 Diabetes and Does Not Cause Weight Gain. Presented at EASD September 14, 2006.
- (4) Canadian Diabetes Association. Type 2 Diabetes: The Basics . (<http://www.diabetes.ca/files/Type2Basics.pdf>).
- (5) Saydah SH, Fradkin J, Cowie CC. 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: October 12, 2006

By: /s/ MALCOLM B. CHEETHAM

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

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