NOVARTIS AG
Form 6-K
September 28, 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 27, 2007**

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

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# Novartis AG

**(Name of Registrant)**

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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):

Yes: o **No**: x

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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 -

**Galvus® receives European approval as new treatment for type 2 diabetes with broad range of indications**

*Galvus delivers robust blood sugar reductions and is well tolerated in a broad range of patients with type 2 diabetes*

*Approved for use in combination with the most common oral anti-diabetes medicines metformin, thiazolidinediones or sulfonylureas*

*More than half of patients currently taking medicines to treat type 2 diabetes are still not reaching their blood sugar goals*

**Basel, September 28, 2007** Galvus® (vildagliptin), a new once-daily oral treatment for patients with type 2 diabetes, has been granted European Union approval. Galvus is the only drug in its class to offer such a broad range of indications for use in combination therapies with other anti-diabetic medicines.

This important approval for Galvus, which is a member of a new class of drugs known as DPP-4 inhibitors, comes as physicians are increasingly searching for new drugs to combine with existing medicines. The European Commission granted approval for Galvus to be used in combination with some of the most frequently prescribed oral anti-diabetes medicines metformin, sulfonylureas (SUs) or thiazolidinediones (TZDs).

The approval applies in all 27 countries of the European Union as well as in Norway and Iceland. The International Diabetes Federation (IDF) Diabetes Atlas estimates that approximately 28 million people in developed countries have type 2 diabetes(1), and more than half of patients with this disease are still not reaching their treatment goals despite undergoing medical treatment[2].

The approval of Galvus is a major milestone for the millions of type 2 diabetes patients across Europe who are being treated but still not reaching optimal blood sugar levels, said Burkhard Göke, MD, of the Department of Gastroenterology at Ludwig-Maximilians-University in Munich, Germany.

Galvus lowers high blood sugar levels with no weight gain and a low incidence of hypoglycemia, two side effects commonly associated with currently available drugs such as SUs and TZDs. With Galvus, we now have another treatment option to help get patients to goal, said Dr. Göke.

Galvus delivers significant blood sugar reductions when used in combination with the most commonly used oral diabetes medicines(3,4,5) in a range of type 2 diabetes patients. These include patients from varied ethnic groups[6], the elderly[7] and those with uncontrolled blood sugar levels(8).

We are delighted that Galvus is approved in Europe for patients with type 2 diabetes, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Our rigorous clinical trial program has demonstrated the robust efficacy and tolerability of Galvus, which offers versatility to physicians looking for new treatment options.

Galvus is already approved 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.

Galvus works through a novel mechanism of action by targeting the dysfunction in the pancreatic islets that cause high blood sugar levels in people with type 2 diabetes. Islet dysfunction, along with insulin resistance, is a contributory factor of type 2 diabetes.

In clinical trials, Galvus demonstrated an overall incidence of side effects similar to placebo. The most common side effects seen in the Galvus clinical program were stuffy nose, headaches, dizziness and upper respiratory tract infection.

Diabetes is a progressive disease that is the fourth leading cause of death in most developed nation(9). When left untreated or not kept under control, type 2 diabetes can lead to heart and kidney disease, blindness and vascular or neurological problems(9).

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as can , or similar expressions, or by express or implied discussions 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 in the US or in any other markets, or for any additional indications or labelling in any 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; 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, 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**

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4. Garber A, et al. Efficacy and Tolerability of Vildagliptin Added to a Sulfonylurea (SU) in Patients with Type 2 Diabetes (T2DM). Presented at ADA, 22-26 June 2007; (Abstract 501-P).

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9. International Diabetes Federation. Diabetes Atlas Third Edition. 2006.

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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 27, 2007

By: /s/ MALCOLM B CHEETHAM

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