NOVARTIS AG
Form 6-K
December 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 December 17, 2007

(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):

Yes: o **No: x**

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Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o **No: x**

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®, a new oral treatment for type 2 diabetes, receives positive opinion following changes to European prescribing information

- *Galvus recommended for use with a sulfonylurea at a 50 mg once-daily dose and with metformin or a thiazolidinedione at a 50 mg twice-daily dose*

- *Revised label includes additional measures proposed by Novartis to support liver safety of patients using Galvus for treatment of type 2 diabetes*

- *Galvus expected to be made available in the first EU countries starting in first half of 2008*

Basel, December 17, 2007 European health authorities have supported changes proposed by Novartis to prescribing information for Galvus® (vildagliptin), opening the way for the formal regulatory approval of these changes as well as the launch in the European Union of this new oral treatment for patients with type 2 diabetes.

Galvus received European Union approval in September 2007 for use in patients in combination with the anti-diabetes medicines metformin, thiazolidinedione (TZD) or a sulphonylurea (SU). This approval included the use of Galvus in 50 mg once-daily, 50 mg twice-daily and 100 mg once-daily doses.

In November 2007, Novartis provided a safety update to European regulators of pooled data that showed liver enzyme elevations were numerically less frequent in patients taking the 50 mg once-daily or 50 mg twice-daily doses compared to the 100 mg once-daily dose.

As a result, Novartis proposed changes to the prescribing information of Galvus to the Committee for Medicinal Products for Human Use. The CHMP has issued a positive opinion recommending approval of Galvus at 50 mg once-daily in combination with an SU, or 50 mg twice-daily in combination with metformin or a TZD. The 100 mg once-daily dose will not be available.

The European Commission generally follows the CHMP s recommendations and is expected to issue a decision within three months. As a result, Galvus is expected to be made available to patients in the first European Union countries in the first half of 2008.

The analysis of pooled data further characterized a known imbalance in liver enzyme levels, resulting in a recommendation not to prescribe Galvus to patients with liver impairment and to conduct liver monitoring at the start of treatment, every three months for the first year, and then periodically thereafter.

As a member of the new class of DPP-4 inhibitors, 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 to type 2 diabetes, a progressive disease in which control of blood sugar deteriorates over time.

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

More than 21,000 patients have participated in the Galvus clinical trial program to date, including approximately 10,000 treated with Galvus. The medicine is currently available in Brazil and Mexico. In February 2007, Novartis received an approvable letter from the US Food and Drug Administration (FDA) and is in discussions with the agency. Novartis will continue working with health authorities to review the recent analysis and to revise prescribing information for Galvus as appropriate.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as expected, will, or similar expressions, or by express or implied discussions regarding the potential launch of Galvus (including any dose thereof) for sale in European markets, potential future approvals of Galvus (or any dose thereof) in other markets, including the US, and potential future revenues from Galvus. Such forward-looking statements reflect the current views of Novartis 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 guarantees that any particular dosage form of Galvus will be approved, Galvus will be launched for sale in any European market or that Galvus (or any particular dose of Galvus) will be approved in the US, any European markets or in any other markets. Nor can there be any guarantee that Galvus will achieve any particular levels of revenue. 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; difficulties or delays in manufacturing or otherwise commercializing the product; litigation; 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 U.S. 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 approximately 100,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) 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.

(2) International Diabetes Federation Diabetes Atlas. Third edition 2006: http://www.eatlas.idf.org/

(3) 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: December 17, 2007

By: /s/ MALCOLM B. CHEETHAM

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