NOVARTIS AG
Form 6-K
February 04, 2008

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 February 1, 2008

(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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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**

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- Investor Relations Release -

Galvus®, a new treatment for patients with type 2 diabetes, receives European approval for label update paving the way for EU launches

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

- *Galvus effectively lowers blood sugar levels and is well tolerated in a broad range of patients with type 2 diabetes*

Basel, February 1, 2008 European health authorities have approved Galvus® (vildagliptin) as a new oral treatment for type 2 diabetes patients, paving the way for launches in Europe. This regulatory approval applies in all 27 countries of the European Union as well as in Norway and Iceland and comes after changes updating the EU label were proposed by Novartis regarding the administration of Galvus.

The European Commission approved Galvus for use in combination with some of the most frequently prescribed oral anti-diabetes medicines metformin, sulphonylureas (SU), or thiazolidinediones (TZD). Galvus can be prescribed as 50 mg once-daily in combination with an SU, or 50 mg twice-daily in combination with metformin or a TZD.

Galvus is not recommended for patients with liver impairment, and liver monitoring should be conducted at the start of treatment, every three months for the first year, and periodically thereafter. Due to limited experience, Galvus is not recommended for patients with moderate or severe renal impairment or congestive heart failure. Galvus should not be used in patients with type 1 diabetes.

The approval of Galvus allows us to move forward with making this important new treatment option available to patients in Europe with type 2 diabetes, said James Shannon, MD, Chief Medical Officer at Novartis Pharma AG. In clinical trials, Galvus has been shown to provide additional efficacy when used in combination with most currently prescribed anti-diabetes medicines across a broad range of patients.

Over 20,000 patients have participated in the Galvus clinical trial program to date, including nearly 13,000 treated with Galvus. When studied in combination with the most widely prescribed type 2 diabetes medicines, Galvus delivered significant blood sugar reductions with a positive tolerability profile in a broad range of patients. The overall incidence of side effects was similar to placebo with the most frequent being stuffy nose, headaches, dizziness and upper respiratory tract infection.

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(1). 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).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, may, should, move forward or similar expressions, or by express or implied discussions regarding the launch of Galvus in Europe, potential future approvals of Galvus in other countries, the safety and efficacy of Galvus, potential new indications or labelling for Galvus or regarding 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 guarantee that Galvus will be approved 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; production delays or business interruption generally; 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 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 provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,200 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Saydah S. et al. Poor Control of Risk Factors for Vascular Disease Among Adults With Previously Diagnosed Diabetes. JAMA 2004: 291(3): 335-342.

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

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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: February 1, 2008

By: /s/ MALCOLM B. CHEETHAM

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