

NOVARTIS AG
Form 6-K
February 27, 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 26, 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:

Edgar Filing: NOVARTIS AG - Form 6-K

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):

Yes: No:

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: 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:

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

- Investor Relations Release -

Eucreas[®], a single-tablet combination of Galvus[®] and metformin, set for launch in first EU countries as new treatment for type 2 diabetes

- *Patients uncontrolled on metformin four times more likely to achieve blood sugar control on Eucreas compared to placebo*
- *First single-tablet combination of a DPP-4 inhibitor and metformin approved for European countries*
- *Eucreas results in no overall weight gain and low incidence of hypoglycemia*
- *Both Eucreas and Galvus to be available to patients in the first EU countries in the next few weeks*

Basel, February 25, 2008 European health authorities have approved Eucreas[®], an oral tablet combining Galvus[®] (vildagliptin) and metformin, as a new treatment for patients with type 2 diabetes. Eucreas is the first single-tablet combination of a member of the new DPP-4 inhibitor class with metformin to be approved in the European Union.

The approval comes after Novartis proposed changes to the EU label recommending that liver monitoring should be conducted at the start of treatment, every three months for the first year, and periodically thereafter. The Eucreas approval closely follows European approval of the updated label for Galvus announced earlier this month.

The decision applies in all 27 countries of the EU as well as in Norway and Iceland, and both medicines will be available in the first European countries within the next few weeks.

Edgar Filing: NOVARTIS AG - Form 6-K

Studies show that more than half of patients currently taking medication to manage their type 2 diabetes are still not reaching blood glucose goals(1). Combination therapy usually becomes necessary due to progressive worsening of blood sugar control during the natural course of the disease(2).

In clinical studies, patients inadequately controlled on metformin, one of the most prescribed oral therapies for type 2 diabetes, were four times more likely to achieve blood sugar control by adding Galvus to their treatment compared to those who added a placebo (or sugar pill)(3). Furthermore, Galvus when administered with metformin resulted in additional blood sugar reductions of 1.1% as measured by HbA1c(4), the gold standard measure of blood sugar control(5).

The approval of Eucreas marks an important step forward in the management of type 2 diabetes, as it is the first single-tablet combination of a DPP-4 inhibitor with metformin for patients in Europe, said James Shannon, MD, Chief Medical Officer at Novartis Pharma AG. The complementary actions of Galvus and metformin, which are the medicines combined in Eucreas, help to bring blood sugar levels under control without the side effects commonly associated with many widely-used type 2 diabetes medicines.

In clinical trials, the addition of Galvus to metformin provided robust blood sugar control without weight gain and with fewer cases of hypoglycemia (i.e. dangerously low blood sugar)(4), side effects associated with other therapies for type 2 diabetes such as sulfonylureas or thiazolidinediones.

Eucreas has been approved for use in type 2 diabetes patients who are inadequately controlled with metformin alone, or are being treated with Galvus and metformin as separate tablets. Eucreas is recommended for use twice-daily at a dose of either 50 mg vildagliptin/850 mg metformin or 50 mg vildagliptin/1000 mg metformin.

Eucreas combines two agents that work together to target both a dysfunction in the pancreatic islets and insulin resistance, two of the main factors contributing to type 2 diabetes. Galvus works through a novel mechanism of action that targets islet dysfunction and restores the body's natural ability to increase insulin and decrease glucagon – the two main hormones controlling blood sugar levels. Metformin works mainly by decreasing the production of sugar by the liver and increasing insulin sensitivity.

Type 2 diabetes is a progressive disease in which control of blood sugar deteriorates over time. If left untreated or not kept under control, it can lead to heart and kidney disease, blindness, and vascular or neurological problems(6).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as likely, to be, will, usually, can or similar expressions, or by express or implied discussions regarding the launch of Galvus and Eucreas in Europe, potential future approvals of Galvus and Eucreas in other countries, potential new indications or labelling for Galvus and Eucreas or regarding potential future revenues from Galvus and Eucreas. 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 and Eucreas to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Galvus and Eucreas will be approved for sale, or for any additional indications or labelling in any market. Nor can there be any guarantee that Galvus and Eucreas will be launched in any particular market, or will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Galvus and Eucreas 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; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; production delays or business interruption generally; 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 Turner RC, Cull CA, Frighi V, Holman RR. Glycemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus: progressive requirement for multiple therapies (UKPDS 49). JAMA 281:2005-2012, 1999.
- 3 Dejager S, et al. Achievement of Glycemic Targets with Vildagliptin. Presented at EASD 17-21 September 2007. (Abstract A-07-899).
- 4 Bosi E, et al. Effects of Vildagliptin on Glucose Control Over 24 Weeks in Patients With Type 2 Diabetes Inadequately Controlled With Metformin. Diabetes Care. 2007; 30:890-895.
- 5 American Diabetes Association. Standards of Medical Care in Diabetes 2006. http://care.diabetesjournals.org/cgi/content/full/29/suppl_1/s4
- 6 International Diabetes Federation Diabetes Atlas. Third edition 2006: <http://www.eatlas.idf.org/>

###

Novartis Media Relations

John Gilardi

Novartis Global Media Relations

+41 61 324 3018 (direct)

+41 79 596 1408 (mobile)

john.gilardi@novartis.com

e-mail: media.relations@novartis.com

Navjot Rai

Novartis Pharma Communications

+41 61 324 6498 (direct)

+41 79 777 6400 (mobile)

navjot.raï@novartis.com

Novartis Investor Relations

International

North America

Edgar Filing: NOVARTIS AG - Form 6-K

Ruth Metzler-Arnold

Jill Pozarek +1 212 830 2445

Katharina Ambuehl

Edwin Valeriano +1 212 830 2456

Pierre-Michel Bringer

Jason Hannon

Thomas Hungerbuehler

Richard Jarvis

Isabella Zinck

Central phone no:+41 61 324 7944

e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com

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 26, 2008

By:

/s/ MALCOLM B. CHEETHAM

Name:
Title:

Malcolm B. Cheetham
Head Group Financial
Reporting and Accounting