

NOVARTIS AG  
Form 6-K  
September 24, 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 21, 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:**  **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):

Edgar Filing: NOVARTIS AG - Form 6-K

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<sup>®</sup>, a single-tablet combination of Galvus<sup>®</sup> and metformin, recommended for EU approval for type 2 diabetes**

*Following approval, Eucreas will be first single-tablet combination of a DPP-4 inhibitor and metformin in EU*

*Recommended approval based on additional robust reduction in blood sugar when Galvus added to metformin*

*Galvus when added to metformin is well tolerated with no weight gain and low incidence of hypoglycemia*

**Basel, September 21, 2007** Novartis has received a positive opinion recommending European Union approval for Eucreas<sup>®</sup>, an oral tablet combining Galvus<sup>®</sup> (vildagliptin) and metformin, as a new treatment for patients with type 2 diabetes. Following approval, Eucreas will be the first single-tablet combination of a DPP-4 inhibitor and metformin approved in the EU.

The positive opinion for Eucreas was issued by the Committee for Medicinal Products for Human Use (CHMP), which reviews medicines for the European Commission (EC). The Commission generally follows the CHMP's recommendations and is expected to issue a decision within three months.

The recommendation was based on data showing additional robust reductions in blood sugar when Galvus, a member of a new class of diabetes medicines called DPP-4 inhibitors, was added to metformin – one of the most prescribed oral anti-diabetes therapies. In clinical studies, Galvus administered in combination with metformin resulted in additional blood sugar reductions of 1.1% as measured by HbA1c(1), the gold standard measure of blood sugar control(2).

Importantly for patients, Galvus, when added to metformin, is also well tolerated. In clinical trials, the addition of Galvus to metformin provided robust blood sugar control without weight gain and with fewer hypoglycemia side effects (i.e. dangerously low blood sugar)(3) than other type 2

diabetes medicines such as sulfonylureas or thiazolidinediones.

The anticipated European approvals of Eucreas and Galvus will allow us to offer new treatment options to patients with type 2 diabetes and to help them gain better blood sugar control, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. With a significant proportion of type 2 diabetics still not reaching their blood sugar goals, Eucreas and Galvus have the potential to help millions of patients, and we are committed to making these treatments available as soon as possible.

Galvus received a positive opinion from the CHMP in July 2007 recommending European approval as an add-on to the most common oral anti-diabetes medicines, with the broadest range of indications for any drug in the DPP-4 class.

Eucreas has been recommended 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 Galvus/850 mg metformin or 50 mg Galvus/1000 mg metformin.

With Eucreas, patients who are not reaching their blood sugar goals on metformin alone will have an effective and well tolerated treatment option to gain better blood sugar control, said Prof Emanuele Bosi, Director of the Diabetes & Endocrinology Unit at San Raffaele University Hospital in Milan, Italy.

Prof Bosi added: In clinical studies Galvus added to metformin demonstrates additional significant blood sugar reductions and is well tolerated. The combination of Galvus and metformin does not cause weight gain and has a low incidence of hypoglycemia, the two most common side effects of current treatments for patients with type 2 diabetes.

Data presented earlier this week at the European Association for the Study of Diabetes (EASD) congress demonstrated that patients inadequately controlled on metformin are four times more likely to achieve blood sugar control with the addition of Galvus compared to placebo (or sugar pill)(4).

A study of 544 patients with type 2 diabetes who were inadequately controlled on metformin showed that 35.5% achieved glycemic control (HbA1c < 7.0%) when Galvus was added to metformin, compared to 9.4% of those receiving metformin with placebo(4). The American Diabetes Association recommends an HbA1c of less than 7.0% to minimize risk of complications in type 2 diabetes patients(2).

Eucreas combines two agents to provide robust blood sugar control by increasing insulin, decreasing glucagon and targeting insulin resistance. 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. Metformin works mainly by decreasing the production of sugar by the liver and increasing insulin sensitivity. In Eucreas, Galvus and metformin work to restore the natural function of the body in controlling blood sugar.

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.

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(5). Studies show that more than half of those currently taking medication to manage their condition are still not reaching their blood glucose goals(6). Due to the progressive worsening of blood sugar control during the natural course of type 2 diabetes, combination therapy usually becomes necessary(7).

**Disclaimer**

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as generally follows , expected , will , potential , following approval , anticipated or similar expressions, or by express or implied discussions regarding

potential future regulatory filings or approvals with respect to, or future sales of, Eucreas and Galvus. Such forward-looking statements reflect the current views of Novartis and 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 Eucreas and Galvus will be approved for sale in the EU or in any additional markets or that Eucreas and Galvus will reach any particular sales levels. In particular, management's expectation regarding Eucreas and Galvus could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, unexpected clinical trial results, including unexpected additional analysis of existing clinical data and unexpected new clinical data; government, industry, and general public pricing pressures; competition in general; the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in Novartis AG's Form 20-F filed 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 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, 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**

- (1) 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.
- (2) American Diabetes Association. Standards of Medical Care in Diabetes 2006. [http://care.diabetesjournals.org/cgi/content/full/29/suppl\\_1/s4](http://care.diabetesjournals.org/cgi/content/full/29/suppl_1/s4)
- (3) Novartis. Data on file.
- (4) Dejager S, et al. Achievement of Glycemic Targets with Vildagliptin. Presented at EASD 17-21 September 2007. (Abstract A-07-899).
- (5) International Diabetes Federation Diabetes Atlas. Third edition 2006: <http://www.eatlas.idf.org/>
- (6) Saydah S, et al. Poor Control of Risk Factors for Vascular Disease Among Adults With Previously Diagnosed Diabetes. *JAMA* 2004; 291(3): 335-342.
- (7) 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.

###





**Novartis Media Relations**

**John Gilardi**

Novartis Global Media Relations  
+41 61 324 3018 (direct)  
+41 79 596 14008 (mobile)  
john.gilardi@novartis.com

**Navjot Rai**

Novartis Pharma Communications  
+41 61 324 6498 (direct)  
+41 79 777 6400 (mobile)  
navjot.raai@novartis.com

e-mail: media.relations@novartis.com

**Novartis Investor Relations**

**International**

**Ruth Metzler-Arnold**  
Katharina Ambuehl  
Nafida Bendali  
Pierre-Michel Bringer  
Jason Hannon  
Thomas Hungerbuehler  
Richard Jarvis

Central phone no: +41 61 324 7944  
e-mail: investor.relations@novartis.com

**North America**

**Ronen Tamir** +1 212 830 2433  
+1 212 830 2445  
Jill Pozarek +1 212 830 2456  
Edwin Valeriano

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: September 21, 2007

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial  
Reporting and Accounting