

NOVARTIS AG
Form 6-K
July 23, 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 July 20, 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):

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 -

Galvus®, a new oral treatment for type 2 diabetes, receives positive opinion recommending European Union approval

- *Galvus delivers significant blood sugar reductions with good tolerability in a range of patients with type 2 diabetes*
- *Recommended for use in combination with the most common oral diabetes medicines – broadest indication in Europe for new class of DPP-4 drugs*
- *Estimated 28 million patients have type 2 diabetes in the European Union(1)*

Basel, July 19, 2007 Novartis has received a positive opinion recommending European Union approval of Galvus® (vildagliptin) as a new once-daily oral medication for type 2 diabetes, a disease affecting an estimated 28 million patients in Europe(1).

The Committee for Medicinal Products for Human Use (CHMP), which reviews medicines for the European Commission, issued the positive opinion based on data from more than 5,700 patients in 13 clinical studies.

This announcement comes on the same day that the CHMP recommended approval for two other Novartis medicines, Aclasta® (zoledronic acid 5 mg) for postmenopausal osteoporosis and Exelon® (rivastigmine transdermal patch) for Alzheimer's disease. So far this year Novartis has received a total of seven product approvals and four positive opinions from the US and European regulatory authorities, providing innovative treatments to patients and creating a strong new growth platform.

The European Commission generally follows the CHMP's recommendations and is expected to issue a decision on Galvus within three months. The decision will apply in all 27 EU member states plus Iceland and Norway.

The clinical trial program showed that Galvus delivered significant blood sugar reductions in a range of patients with type 2 diabetes(2),(3). Furthermore, Galvus provided additional efficacy when added to the most commonly used oral diabetes medicines(4),(5),(6).

Galvus is recommended in the EU for use in combination with the most common oral diabetes medicines – metformin, a thiazolidinedione (TZD) or a sulfonylurea (SU) – the broadest proposed indication for any member of the new DPP-4 inhibitor class of drugs.

When studied in combination with the most widely-used diabetes medicines, Galvus showed a positive safety and tolerability profile(4),(5),(6). The most frequent side effects seen in the Galvus clinical program were stuffy nose, headaches and dizziness(7).

Galvus is an important new treatment option for controlling type 2 diabetes because it provides beneficial blood sugar reductions without many of the side effects seen with other diabetes medications, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Many type 2 diabetes patients need more than one treatment to bring their blood sugar levels under control, therefore the efficacy and tolerability of Galvus in combination with other medicines is especially significant.

More than 21,000 patients have participated in the Galvus clinical trial program to date, including approximately 10,000 treated with Galvus. The recommended dose of Galvus is 100 mg once-daily when used in combination with metformin or a TZD, and 50 mg once-daily in combination with an SU.

The positive opinion and recommended label in Europe reflect the depth and breadth of preclinical and clinical data for vildagliptin as one of the most widely studied DPP-4 inhibitors, said Bo Ahren, MD, Head of the Research Department at Lund University Hospital, Sweden. The clinical trial program has shown vildagliptin to be safe, effective and well tolerated across a range of patients. This new treatment option has the potential to make a difference for the many millions of patients who suffer from type 2 diabetes and are still not achieving their blood sugar goals using existing treatments.

Galvus is available in Brazil and Mexico. In February 2007, Novartis received an approvable letter from the US Food and Drug Administration. Novartis has submitted a proposal to the FDA for additional studies in renally impaired patients to also confirm good tolerability in this patient group. Skin lesions, as seen in monkeys, have not been seen either in healthy volunteers or in patients in the Galvus clinical trial program involving clinical studies lasting up to two years.

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.

In most developed nations, diabetes is the fourth leading cause of death(8). 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(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(8).

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 , potential , or similar expressions, or by express or implied discussions regarding potential future regulatory filings or approvals with respect to, or future sales, of 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 Galvus will be approved for sale in the EU, the US or in any additional markets or that Galvus will reach any particular sales levels. In particular, management's expectation regarding Galvus could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, unexpected clinical trial results, including additional analysis of existing clinical data and 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 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 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) 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) Rosenstock J. et al. Consistent Efficacy and Safety of Vildagliptin Monotherapy Across Ethnicities Presented at ADA, 22-26 June 2006; (Abstract 2141-PO).
- (3) Pratley R. et al. Benefit/Risk Assessment of Vildagliptin in the Elderly; Pooled Analysis of 5 Monotherapy Studies. Presented at ADA, 22-26 June 2007; (Abstract 507-P).
- (4) Garber A. et al. Vildagliptin Added to Metformin Improves Glycemic Control and May Mitigate Metformin-Induced GI Side Effects in Patients with Type 2 Diabetes (T2DM). Presented at ADA, 9-13 June 2006; (Abstract 121-OR).
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- (6) Rosenstock J. et al. Efficacy and tolerability of initial combination therapy with vildagliptin and pioglitazone compared with component monotherapy in patients with type 2 diabetes. *Diabetes, obesity & metabolism* 2007; 9(2):175-85.
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Novartis Media Relations

Corinne Hoff

Novartis Global Media Relations
+41 61 324 9577 (direct)
+41 79 248 5717 (mobile)
corinne.hoff@novartis.com

Richard Booton

Novartis Pharma Communications
+41 61 324 4356 (direct)
+41 79 753 2593 (mobile)
richard.booton@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

International

| | |
|----------------------------|-----------------|
| Ruth Metzler-Arnold | +41 61 324 7944 |
| Katharina Ambühl | +41 61 324 5316 |
| Nafida Bendali | +41 61 324 3514 |
| Jason Hannon | +41 61 324 2152 |
| Thomas Hungerbuehler | +41 61 324 8425 |
| Richard Jarvis | +41 61 324 4353 |

North America

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

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: July 20, 2007

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial
Reporting and Accounting