

NOVARTIS AG
Form 6-K
June 26, 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 June 25, 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:

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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):

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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
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- Investor Relations Release -

New data from multiple studies show Galvus® delivers consistent and robust blood sugar control in patients with type 2 diabetes

Significant blood sugar reductions seen across range of patient populations, including varied ethnic groups, the elderly, and those at high risk of developing diabetes

Galvus lowers blood sugar when added to a sulfonylurea, reinforcing efficacy in combination with commonly used diabetes medicines

Data confirm good tolerability in humans with studies showing incidence of side effects similar to placebo in monotherapy trials

European regulatory decision anticipated by end 2007; discussions continue on steps to gain US approval

Basel, June 25, 2007 Galvu® (vildagliptin), a new once-daily oral treatment for type 2 diabetes submitted for approval in the US and Europe, has been shown in new clinical data to deliver consistent and robust blood sugar reductions in patients with this progressive disease estimated to affect about 246 million people worldwide⁽¹⁾.

The findings, presented at the 67th Annual Scientific Sessions of the American Diabetes Association (ADA), are consistent with earlier results demonstrating the efficacy and tolerability of Galvus both as a monotherapy and when added to many commonly used diabetes medicines in a range of patients across the type 2 diabetes disease spectrum^{(2),(3),(4)}. These include varied ethnic groups⁽³⁾ and the elderly⁽⁴⁾ as well as patients with impaired glucose tolerance at high risk of developing diabetes⁽⁵⁾ and those with uncontrolled blood sugar levels⁽⁶⁾.

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These results further reinforce the clinical benefits of Galvus as an important new treatment option for patients with type 2 diabetes, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. We remain convinced that Galvus is safe and effective and will continue to work with health authorities to ensure this medicine can be made available to patients worldwide as soon as possible.

A member of a new class of diabetes medicines called DPP-4 inhibitors, Galvus is currently approved in Brazil and Mexico. A European regulatory decision is anticipated by the end of 2007. In the US, Novartis received an approvable letter in February 2007, and discussions are ongoing with the US Food and Drug Administration on steps needed to move forward to approval.

New data presented at the ADA showed that Galvus, when added to the sulfonylurea glimepiride, produced an additional significant blood sugar reduction of 0.6% in HbA1c compared to glimepiride

alone⁽²⁾. HbA1c is a measure of plasma glucose levels over the preceding three months, and indicates how well diabetes is being controlled over time.

These data supplement existing findings with Galvus when used in combination with widely prescribed diabetes medicines such as metformin, an oral thiazolidinedione (TZD) and insulin.

In the Galvus clinical program no evidence has been seen of overall weight gain⁽⁷⁾ or hypoglycemia (dangerously low blood sugar levels)⁽⁸⁾, side effects commonly associated with some type 2 diabetes medications. The overall incidence of side effects, including edema (fluid retention), was similar to placebo in monotherapy trials⁽⁸⁾.

Taken together, these data provide evidence that vildagliptin could provide a safe, effective and well-tolerated therapy when used alone or in combination with other anti-diabetic therapies, said Alan J. Garber, MD, Ph.D, Professor of Medicine, Biochemistry and Molecular Biology, and Molecular and Cellular Biology at the Baylor College of Medicine in Houston, Texas. The majority of patients with type 2 diabetes have not achieved their A1c goals and it may therefore be helpful to have additional therapeutic options such as vildagliptin.

In most developed nations, diabetes is the fourth leading cause of death⁽⁹⁾. 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⁽¹⁰⁾. When left untreated or not kept under control, type 2 diabetes can lead to heart and kidney disease, blindness, and vascular or neurological problems⁽¹⁾.

Galvus works through a novel mechanism of action, targeting a dysfunction in the pancreatic islets that causes high blood sugar levels in people with type 2 diabetes. In clinical studies, Galvus has demonstrated significant reductions in blood sugar sustained at two years⁽⁸⁾.

At a special ceremony during the congress, Novartis presented its 9th annual Novartis Prize in Diabetes to recognize five recipients for innovative patient-oriented diabetes research. For more information about the Novartis Prize in Diabetes, please visit www.diabetesaward.novartis.com.

Disclaimer

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as anticipated, , continue, could, may, will or by express or implied discussions regarding potential future regulatory approvals or future sales of 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any future regulatory filings will satisfy regulatory requirements regarding Galvus, that

Galvus will be approved by regulatory authorities for any indication, that Galvus will be brought to market in the EU, the US or any additional market or that Galvus will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of Galvus could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays in government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures, as well as the additional risks and 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 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. Diabetes Atlas. Third Edition 2006.
- (2) Garber, A J et al. Efficacy and Tolerability of Vildagliptin Added to a Sulfonylurea (SU) in Patients with Type 2 Diabetes (T2DM). Presented at ADA 22-26 June 2007 (501-P).
- (3) Rosenstock, J et al. Consistent Efficacy and Safety of Vildagliptin Monotherapy Across Ethnicities. Presented at ADA 22-26 June 2007 (2141-PO).
- (4) Pratley, R E et al. Benefit/Risk Assessment of Vildagliptin in the Elderly: Pooled Analysis of 5 Monotherapy Studies. Presented at ADA 22-26 June 2007 (507-P).
- (5) Rosenstock, J et al. Effects of Vildagliptin in Subjects with IGT. Presented at ADA 22-26 June 2007 (505-P).
- (6) Scherbaum, W A et al. Efficacy and Tolerability of Vildagliptin in Drug-Naïve Patients with Type 2 Diabetes (T2DM) and Mild Hyperglycemia. Presented at ADA 22-26 June 2007 (503-P).
- (7) Foley, J E et al. Effect of Vildagliptin Monotherapy on Body Weight in Drug-Naïve Patients With Type 2 Diabetes (T2DM). Presented at IDF, December 2006 (Abstract 826).
- (8) Novartis. Data on file.
- (9) International Diabetes Federation. Did You Know? 2007: <http://www.idf.org/home/index.cfm?node=37>
- (10) Saydah, S H 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: June 25, 2007

By: /s/ MALCOLM B. CHEETHAM

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