NOVARTIS AG
Form 6-K
September 19, 2006

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 14, 2006

(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

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: 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

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
hppt://www.novartis.com

- Investor Relations Release -

Galvus® demonstrates powerful blood sugar reductions in Phase III studies without the side effects associated with many anti-diabetic drugs

- *Efficacy of oral treatment Galvus comparable to an insulin sensitizer (TZD) in clinical trials, shows a 1.8% reduction in average blood sugar (HbA1c) as monotherapy*

- *Unlike some anti-diabetic drugs, Galvus shows very low incidence of hypoglycemia (low blood sugar) and edema (fluid retention) and also no weight gain overall*

- *New data confirm effectiveness of once-daily dosing*

- *Diabetes already the fourth leading cause of death in most developed countries; number of diabetes patients in the developing world projected to rise by 170% by 2025*

Basel, September 14, 2006 Galvus® (vildagliptin), submitted for US and EU approval as a once-daily oral treatment for type 2 diabetes, has demonstrated impressive efficacy and an attractive tolerability profile that may benefit many people currently struggling to control their disease.

These findings from Phase III studies were presented at the 42nd European Association for the Study of Diabetes (EASD) meeting in Copenhagen, Denmark.

Galvus showed equivalent efficacy to the diabetes medicine rosiglitazone, an insulin sensitizer known as a thiazolidinedione (or TZD), in a head-to-head monotherapy study that led to an overall 1.8% reduction in blood sugar levels as measured by HbA1c (A1c). The results were achieved without weight gain overall and with a lower incidence of edema (fluid retention) both of which are side effects commonly associated with TZDs(1).

Patients and physicians need additional therapies that address the primary cause of diabetes, which is pancreatic islet dysfunction, said Professor Emanuele Bosi, Director of the Diabetes & Endocrinology Unit at San Raffaele University Hospital in Milan, Italy.

Vildagliptin has been tested in combination with many currently available drugs, resulting in effective A1c reductions with an excellent side-effect profile. Many patients and physicians have come to unfortunately regard the side effects of current therapies as normal and accept them as part of their treatment. These results are very reassuring for patients who have to take medications to treat their diabetes for a long time, said Professor Bosi.

Even among people receiving diabetes care, controlling blood sugar levels is difficult. More than half of those currently taking medicines for diabetes are still not reaching their blood sugar targets, according to the

National Health and Nutrition Examination Survey (NHANES)(2). Diabetes is a progressive disease where blood sugar control deteriorates over time, failure to properly control diabetes can lead to heart and kidney disease, blindness, vascular and neurological problems(3),(4).

Type 2 diabetes currently affects about 230 million people worldwide and is expected to grow to more than 350 million by 2025, according to the International Diabetes Federation. While the disease burden among Western nations is great, the IDF projects a 170% increase in type 2 diabetes cases in the developing world by 2025(4).

Galvus, a member of the DPP-4 inhibitor class, works through a novel mechanism of action targeting the pancreatic islet dysfunction that causes high blood sugar levels in people with type 2 diabetes. Islet dysfunction can specifically lead to excess sugar production (via glucagon from the alpha-cells) and reduced insulin production (from the beta-cells). Galvus affects both pancreatic alpha- and beta-cells, improving their ability to appropriately sense and respond to sugar in the blood.

The European marketing application for Galvus was filed in August 2006, while the US submission was completed in March 2006. The submissions included data from clinical trials involving more than 5,400 patients worldwide.

Trial data at EASD underscore effective once-daily treatment

The four highlighted trials at EASD were part of a broad overview of clinical data summarizing the development as well as overall efficacy and tolerability of Galvus. A total of 17 clinical and preclinical Galvus investigations were part of the congress scientific program.

Clinical trials have consistently shown that Galvus provides significant efficacy with good tolerability in a variety of patients, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. We are extremely excited that the Galvus profile could change the management of type 2 diabetes for many millions of people around the world.

The head-to-head monotherapy comparison of Galvus (100 mg daily) and rosiglitazone (8 mg daily) involved 697 patients in a six-month study. Galvus reduced blood sugar levels significantly as measured by A1c and was comparable to the TZD, particularly in high baseline patients (-1.8%). Galvus treatment was not associated with weight gain overall, while people in the rosiglitazone group gained on average 1.6 kg. Galvus-treated patients also experienced a lower incidence of edema (2.5% vs. 4.9%)(1). (EASD abstract #0789)

In another study presented at EASD, a treatment combination of Galvus and the TZD pioglitazone resulted in 65% of patients on Galvus achieving the American Diabetes Association (ADA)-defined A1c blood sugar goal of less than 7% compared to 42% of those who achieved this goal on monotherapy treatment (Galvus 42.5% or pioglitazone 42.9%). Side effects were consistent with the individual tolerability profiles of Galvus and TZDs, while the combination was also well tolerated(5). (EASD abstract #0801)

A new dose-ranging study presented at EASD concluded that Galvus taken once-daily was effective in lowering A1c levels. The trial of 279 patients who had not been treated previously with diabetes medicines found similar, significant A1c reductions among patients taking Galvus 100 mg daily, regardless of whether this was given as a once-daily dose or as 50 mg twice-daily(6). (EASD abstract #0791)

Another presentation showed positive results of a 24-week trial when Galvus was combined with metformin, another commonly prescribed diabetes medicine. The results showed a 1.1% reduction in blood sugar level as measured by A1c when compared to metformin alone(7). Galvus was also very well tolerated in this study(7). (EASD abstract #0793)

Throughout the clinical development program, Galvus has shown no weight gain overall. In one study, obese patients treated with Galvus demonstrated a relative weight benefit of 2.8 kg compared to those

taking TZDs(3). This is potentially important since many people with type 2 diabetes often struggle to keep their weight under control.

Galvus has also demonstrated a good tolerability profile with a very low incidence of hypoglycemia (excessively low blood sugar) and edema (fluid retention) in monotherapy trials. The most commonly seen side effects in clinical studies with Galvus include cold/flu like symptoms, headache and dizziness(3).

The GLORIOUS mega-trial program

Novartis is committed to developing therapies that will impact the progression of type 2 diabetes and recently announced the commencement of the GLORIOUS mega-trial program, one of the largest series of outcomes-focused clinical programs conducted among people with type 2 diabetes. Novartis intends to provide additional details on the program later in 2006.

Disclaimer

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as submitted for US and EU approval, may, could , potentially , committed , intends , or similar expressions, or by express or implied discussio regarding potential future regulatory approvals or future sales of Galvus. Such forward-looking statements 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 any market, or that Galvus will reach any particular level of sales. In particular, management s expectations regarding Galvus could be affected by, among other things, unexpected regulatory actions or delays in government regulation generally; competition in general; unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; government, industry, and general public pricing pressures; as well as the additional 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, treat 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. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. 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. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland; Novartis Group companies employ approximately 97,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) A. Schweizer, S. Dejager, M.A. Baron, D. Mills, Y. Amiour, J. Rosenstock. Vildagliptin is as Effective as Rosiglitazone in Drug-Naïve Patients with Type 2 Diabetes and Does Not Cause Weight Gain. Presented at EASD September 14, 2006

(2) S.H. Saydah, J. Fradkin, C.C. Cowie. Poor Control of Risk Factors for Vascular Disease Among Adults with Previously Diagnosed Diabetes. *JAMA* 2004; 291(3):335-342.

(3) Data on file, Novartis Pharma AG

(4) http://www.idf.org/home/index.cfm?node=37, accessed March 9, 2006

(5) J. Rosenstock, M.A. Baron, B. Bassiri, E. Rochotte, F. Cressier, Y. Amiour, C. Hsu, R.-P. Camisasca, S. Dejager, A. LeBeaut. Efficacy of Vildagliptin Combined with Pioglitazone in Patients with Type 2 Diabetes. Presented at EASD September 14, 2006

(6) S. Dejager, M.A. Baron, S. Razac, J.E. Foley, S. Dickinson, A. Schweizer. Efficacy of Vildagliptin in Drug-naïve Patients with Type 2 Diabetes. Presented at EASD September 14, 2006

(7) E. Bosi, C. Collober, E. Rochotte, R.-P. Camisasca, A.J. Garber. Vildagliptin added to Metformin Improves Glycaemic Control by Decreasing Fasting and Postprandial Glucose in Patients with Type 2 Diabetes. Presented at EASD September 14, 2006

# # #

Media contacts

John Gilardi

Novartis Global Media Relations

+41 61 324 3018 (direct)

+41 79 596 1408 (mobile)

john.gilardi@novartis.com

Richard Booton

Novartis Pharma Communications

+41 61 324 4356 (direct)

+41 79 753 2593 (mobile)

richard.booton@novartis.com

Investor Relations

International: +41 61 324 7944

North America: +1 212 830 24 33

investor.relations@novartis.com

5

Novartis International AG
Novartis Global Communications
CH-4002 Basel
Switzerland
hppt://www.novartis.com

- Investor Relations Release -

FTY720 shows significant benefits in helping MS patients over one year in Phase II data published in *New England Journal of Medicine*

- *Oral treatment for multiple sclerosis (MS) maintains significant reductions in inflammatory disease activity and clinical relapses for up to one year*
- *Comprehensive Phase III program now underway worldwide*
- *24-month Phase II treatment data to be presented at European Congress for Treatment and Research in Multiple Sclerosis (ECTRIMS) in September*
- *More than two million people estimated to suffer from multiple sclerosis, one of the leading causes of neurological disability in young adults(1)*

Basel, September 13, 2006 Clinical trial results published in the *New England Journal of Medicine* showed significant benefits for patients suffering from relapsing multiple sclerosis (MS) who were treated with FTY720 (fingolimod), in development with potential to become the first orally effective compound to help patients with this debilitating neurological disease.

The Phase II trial data showed that FTY720 taken once-daily during the initial six months of treatment reduced the rate of inflammatory disease activity as measured by magnetic resonance imaging (MRI) by up to 80% and cut clinical relapses by more than 50% compared to placebo(2).

In patients who continued taking FTY720 during the subsequent six-month extension, low levels of disease activity were maintained as measured by both MRI and relapses. Both these measures also decreased in patients who switched from placebo to FTY720.

These results demonstrate that once-daily oral FTY720 provides an improvement in MRI measures of inflammation as well as in relapse-related clinical endpoints in patients with relapsing multiple sclerosis, said Professor Ludwig Kappos, chief trial investigator and head of the Department of Neurology at the University Hospital in Basel, Switzerland.

If the magnitude of benefits shown in this Phase II study is confirmed in the larger-scale Phase III program, oral FTY720 could potentially have a major impact in the way MS will be treated in the future, said Professor Kappos.

Phase III clinical trials program underway

Based on the positive Phase II results, Novartis launched earlier in 2006 a Phase III clinical trials program called FREEDOMS (FTY720 Research Evaluating Effects of Daily Oral therapy in Multiple Sclerosis). This 24-month, randomized, double-blind, placebo-controlled study program is designed to include over 2,000 patients worldwide with the relapsing-remitting form of multiple sclerosis between ages 18 and 55. Study participants will be randomized equally to either receive once-daily treatment with 1.25 mg or 0.5 mg of FTY720 or placebo for up to 24 months.

MS affects more than two million people worldwide

More than two million people worldwide are estimated to suffer from MS, which is one of the leading causes of neurological disability in young adults. It is the most common inflammatory and neurodegenerative disorder of the central nervous system, including the brain, spinal cord and optic nerves(3).

The symptoms of MS can range from tingling, numbness, pain, slurred speech and blurred or double vision, to muscle weakness, poor balance or coordination, and tremors. These symptoms can have a significant impact on the patient s employment, social activities and overall quality of life.

Conventional first-line multiple sclerosis therapies offer an average reduction in relapse rates in the range of 30-35% in two-year studies. These medicines also require frequent injections, ranging from daily to weekly(4),(5),(6).

FTY720 is the first in a new class of disease-modifying treatments called sphingosine 1-phosphate receptor (S1P-R) modulators and has a novel mode of action different from all currently marketed MS therapies. FTY720 has been developed by Novartis and licensed from Mitsubishi Pharma Corporation.

An analysis of two-year Phase II data with FTY720 will be presented at the European Congress for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Madrid in September 2006.

Phase II study results in NEJM

The Phase II study described in the *New England Journal of Medicine* was conducted at 32 centers in 11 countries (in Europe and Canada) to evaluate the effect of FTY720 on disease activity as measured by MRI and clinical relapses as well as safety and tolerability.

In the initial placebo-controlled phase, 281 patients were randomized equally to receive FTY720 (1.25 mg or 5 mg) or placebo once-daily for six months. Of the 255 patients who completed this part of the study, 98% volunteered to continue in the extension phase(7). Patients in the placebo group were then re-randomized to receive either 1.25 mg or 5 mg of FTY720 and were blinded for an additional six months. Those already on FTY720 continued with their original treatment.

The study showed that oral FTY720 provided significant and rapid improvement in MRI measures of inflammation and in relapse-related clinical endpoints in patients with relapsing MS. Inflammatory disease activity as measured by the total cumulative number of gadolinium (Gd) enhancing MRI lesions was significantly reduced by up to 80% ($p<0.001$ in FTY720 1.25 mg, $p<0.006$ in FTY720 5 mg) compared to placebo over six months of treatment. At six months, the proportion of patients free of Gd-enhancing lesions was also greater in both FTY720 groups compared to placebo ($p<0.001$ for both groups), with a separation between the curves becoming evident from two months onwards.

Relapse rates were reduced by 55% in the FTY720 1.25 mg group ($p=0.009$) and by 53% in the FTY720 5 mg group ($p=0.014$) compared to placebo. Time to first confirmed relapse was also significantly prolonged in both FTY720 groups compared to placebo ($p=0.007$ in FTY720 1.25 mg, $p=0.01$ in FTY720 5 mg)(8).

In both groups taking FTY720 (i.e. 1.25 mg or 5 mg), patients who had experienced a reduction in their annualized relapse rate of more than 50% compared to placebo during the first six months of the study maintained this low relapse rate during the subsequent six months of the extension(9). More than 80% of patients who received FTY720 for up to 12 months were free from lesions showing active inflammation on MRI at month 12, irrespective of their treatment dose(9).

In patients who switched from placebo to either dosage of FTY720 after six months, the annualized relapse rate was reduced by at least 70% during the six-month extension compared to the period on placebo(9).

In the six month placebo-controlled phase of the study, the most frequent adverse events reported for FTY720 were dose-dependent upper respiratory tract infections (mainly nasopharyngitis) and dyspnea, plus

diarrhea, and nausea(10). FTY720 treatment was associated with initial dose-dependent decreases in heart rate and expiratory flow. Clinically asymptomatic increases in alanine aminotransferase (liver enzyme) and increase in blood pressure were also observed. There were no unexpected safety findings during the six-month extension phase as compared to the six-month placebo-controlled phase(11). The ongoing Phase III study program includes comprehensive safety monitoring which will provide further assessment on the safety profile.

Disclaimer

This release contains certain forward-looking statements relating to Novartis business, which can be identified by the use of forward-looking terminology such as to be presented , potential to become , if the magnitude of benefits confirmed , could potentially , will , or similar express or by express or implied discussions regarding potential future regulatory submissions or approvals or regarding potential future revenue from fingolimod. 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 fingolimod to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that fingolimod will be submitted for approval or will be approved for sale for any indications or labeling in any market. Nor can there be any guarantee that fingolimod will achieve any sales or any particular level of sales. In particular, management s expectations regarding fingolimod could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data or new clinical data; unexpected regulatory actions or delays or government regulation generally; Novartis ability to obtain or maintain patent or other proprietary intellectual property protection; 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 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 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 has been a leader in the neuroscience area for more than 50 years, having pioneered early breakthrough treatments for Alzheimer s disease, Parkinson s disease, attention deficit/hyperactivity disorder, epilepsy, schizophrenia and migraine. Novartis continues to be active in the research and development of new compounds, and is committed to addressing unmet medical needs and to supporting patients and their families affected by these disorders.

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat 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. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. 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. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 97,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Multiple Sclerosis International Federation (http://www.msif.org/en/ms_the_disease/index.html

(2) N Engl J Med, 355;11, www.NEJM.org, September 14, page 1130 (Table 2)

(3) Multiple Sclerosis International Federation (http://www.msif.org/en/ms_the_disease/index.html

(4) L.D. Jacobs et al. Intramuscular Interferon beta-1a for disease progression in relapsing multiple sclerosis. Ann Neurol 1996, 39: 285-294.

(5) IFNB Multiple Sclerosis Study Group. Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. I. Clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. Neurology 1993; 43: 655-661.

(6) K.P. Johnson et al. Copolymer 1 reduces relapse rate and improves disability in relapsing-remitting multiple sclerosis: Results of a phase III multicenter, double-blind, placebo-controlled trial. Neurology 1995; 45: 1268-1276.

(7) N Engl J Med, 355;11, www.NEJM.org, September 14, page 1128 (Figure 1)

(8) N Engl J Med, 355;11, www.NEJM.org, September 14, page 1131 (Table 2B)

(8) N Engl J Med, 355;11, www.NEJM.org, September 14, page 1133 (Table 3)

(10) N Engl J Med, 355;11, www.NEJM.org, September 14, page 1134-1135 (Table 4 and 4B)

(11) N Engl J Med, 355;11, www.NEJM.org, September 14, page 1136 (Table 5)

# # #

Media contacts

John Gilardi

Novartis Global Media Relations
+41 61 324 3018 (direct)
+41 61 324 2200 (main)
john.gilardi@novartis.com

Irina Ferluga

Novartis Pharma Communications
+ 41 61 324 24 22 (direct)
+ 41 79 824 11 21 (mobile)
irina.ferluga@novartis.com

Investor Relations contacts

International: +41 61 324 79 44

North America: +1 212 830 24 33

e-mail: investor.relations@novartis.com

9

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 14, 2006

By: /s/ MALCOLM B. CHEETHAM

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