NOVARTIS AG
Form 6-K
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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 April 6, 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: ý Form 40-F: o

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Investor Relations

Novartis International AG

CH-4002 Basel

Switzerland

Novartis Corporation

608 Fifth Avenue

New York, NY 10020

USA

- Investor Relations Release -

Phase II data for FTY720 shows sustained efficacy and good tolerability over 18 months in patients with relapsing multiple sclerosis (MS)

MS is the leading cause of neurological disability in young adults high unmet need for effective and convenient therapies

Basel, April 6, 2006 Data from the extension of a Phase II study to 18 months support the significant effects of FTY720 (fingolimod), a novel once-daily oral compound in development for treatment of relapsing-remitting multiple sclerosis (MS). More than two million people worldwide are estimated to suffer from MS, which is the leading cause of neurological disability in young adults(1) and affects twice as many women as men.

The data, presented at the American Association of Neurology (AAN) meeting, showed that both patient groups taking FTY720 (1.25 mg and 5 mg) who had experienced more than a 50% reduction in their annualized relapse(2) rate during the study s first six months compared to placebo maintained this low relapse rate during the subsequent 12-month extension.

Currently marketed MS therapies afford an average reduction in relapse rates of only 30% in two-year studies and require frequent injections ranging from daily to weekly(3),(4),(5),(6).

In patients who switched from placebo to either the 1.25 mg or 5 mg dosing of FTY720 after six months, the annualized relapse rate was reduced to a similar extent during the subsequent twelve-month extension phase of the study compared to the first six months on placebo. At month 18, Magnetic Resonance Imaging (MRI) scans were performed in a subgroup of patients. Consistent with what was seen in MRI scans at month six, the vast majority of patients were free from lesions showing active inflammation at month 18.

We are very encouraged to see that the effects of fingolimod in significantly reducing both clinical relapses and inflammatory disease activity are maintained over 18 months, said Dr. Paul O Connor, MD, St. Michael s Institute, Toronto, Canada. We hope that the magnitude of benefits shown in the Phase II study can be confirmed in the larger-scale Phase III study program, which is currently being initiated.

The most frequently reported adverse events in patients treated up to 18 months were non-serious infections (colds, influenza) and headache. Effects initially seen in the first six months of treatment (i.e. first dose heart rate reduction, increase in blood pressure, alteration in liver function, mild increase in airway resistance) did not appear to progress with continued dosing beyond six months. There were also no unexpected safety findings during the extension phase compared to the six-month placebo-controlled phase. All patients in the extension study are now continuing with the

1.25 mg dose since both the 5 mg dose, which had a higher rate of adverse events, and 1.25 mg doses were equally effective in reducing disease activity.

Phase II study design

The results are from a large Phase II study conducted at 32 centers in 11 countries (Europe and Canada). In the initial, placebo-controlled part of this study, 281 patients were randomized in equal numbers to receive either placebo, 1.25 mg or 5 mg of FTY720 orally once-daily for six months. The study evaluated the effect of FTY720 on disease activity as measured by MRI and clinical relapses as well as its tolerability and safety. After six months, patients had the option to enter the extension phase evaluating the longer-term effects. Patients in the placebo group were re-randomized to receive either 1.25 mg or 5 mg, while patients already on FTY720 continued their originally-assigned treatment. Having completed the 12 month time point, the 5 mg dose arm was discontinued and patients previously receiving this dose were continuing in the study on a dose of 1.25mg.

Analysis of the 24-month data is expected to be presented at a key neurological congress in the second half of 2006.

Phase III study program

Novartis has initiated its first Phase III pivotal study called FREEDOMS (**F**ingolimod **R**esearch **E**valuating **E**ffects of **D**aily **O**ral therapy in **M**ultiple **S**clerosis). The 24-month, randomized, double-blind, placebo-controlled FREEDOMS study will include more than 1,000 patients with relapsing-remitting MS between age 18-55. Study participants will be equally randomized to either receive either 1.25 mg or 0.5 mg of FTY720 or placebo once daily for up to 24 months.

This study has begun enrolling patients in several European countries. Novartis is currently in discussions with the US Food and Drug Administration (FDA) on Phase III initiation in the US.

Oral fingolimod has a novel mode of action different from all available MS therapies. If the Phase III clinical program confirms the promise of the Phase II results, oral fingolimod could represent a major improvement in the way MS will be treated in the future, said chief investigator Professor Ludwig Kappos, MD, Department of Neurology at the University Hospital in Basel, Switzerland.

About FTY720 (fingolimod)

FTY720 binds to the sphingosine 1-phosphate receptor-1 (S1P1) on a proportion of circulating lymphocytes and reversibly traps them in the lymph nodes. As a result, FTY720 lowers the number of activated T-cells circulating to the blood stream and central nervous system (CNS), which reduces neuroinflammation and myelin damage in the brain and spinal cord. Under FTY720 treatment, many components of normal lymphocyte function are unaffected and can be activated as part of the immune response within the lymph nodes and other tissues. FTY720 has been developed by Novartis Pharma and licensed from Mitsubishi Pharma Corporation.

About Multiple Sclerosis

MS is the most common inflammatory and neurodegenerative disorder of the central nervous system, including the brain, spinal cord and optic nerves(7). MS typically presents itself in relapsing forms. The relapsing-remitting (RRMS) course is the most common form of the disease. Patients suffer acute self-limiting attacks (relapses) of neurological dysfunction followed by complete or incomplete remission in function. Over time, transmission of electrical nerve impulses is disrupted, nerve cells are destroyed, and patients experience symptoms ranging from fatigue, tingling, numbness and blurred vision to poor muscle control with partial or complete paralysis, speech or

mental impairment. About 50% of patients advance to the secondary progressive (SPMS) course within 10 years(8).

This release contains certain forward-looking statements relating to Novartis business, which can be identified by the use of forward-looking terminology such as encouraged , hope , expected , will , could , or similar expressions, or by express or implied statements regarding the poten long-term impact of a patient s use of fingolimod, the potential commencement of Phase III studies of fingolimod in the US, the potential regulatory approval of fingolimod in any jurisdiction, or 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 Phase III studies of fingolimod will be permitted to commence in the US, or that fingolimod will be approved for any indications or labeling in any market. Nor can there be any guarantee of potential future sales of fingolimod. Neither can there be any guarantee regarding the long-term impact of a patient s use of fingolimod. In particular, management s expectations regarding fingolimod could be affected by, among other things, unexpected clinical trial results, including new clinical trial results and additional analysis of existing results; 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, 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 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 91,000 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/quick_facts.html)

(2) A relapse refers to the appearance of new symptoms or the aggravation of old ones, lasting for at least 24 hours.

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(4) LD 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.

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(8) Weinshenker BG. Natural history of multiple sclerosis. Ann Neurol 1994, 36: S6-S11.

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Novartis Global Investor Relations

Karen J. Huebscher, Ph.D. +41 61 324 84 33

International office

Katharina Ambühl	+41 61 324 53 16
Nafida Bendali	+41 61 324 35 14
Richard Jarvis	+41 61 324 43 53
Silke Zentner	+41 61 324 86 12

e-mail: investor.relations@novartis.com

Fax: +41 61 324 84 44
www.novartis.com

North American office

Ronen Tamir +1 212 830 24 33

Jill Pozarek +1 212 830 24 45

e-mail: investor.relations@novartis.com

Fax: +1 212 830 24 05
www.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: April 6, 2006

By: /s/ MALCOLM B. CHEETHAM

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