

NOVARTIS AG  
Form 6-K  
April 14, 2010

# 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 13, 2010

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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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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Yes:  No:

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**Novartis International AG**

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**- Investor Relations Release -**

**Novartis investigational multiple sclerosis therapy Gilenia®\* (FTY720) shown to reduce relapse rates regardless of treatment history**

- *Data presented at the American Academy of Neurology show annual relapse rates reduced by 62% in newly treated patients*
- *Relapse rates reduced by 44% in previously treated patients*
- *New extension data show Gilenia effect sustained over two years; also highlights potential benefits of switching from interferon beta-1a*
- *US and EU regulatory reviews underway for 0.5 mg once-daily dose of Gilenia*

**Basel, April 13, 2010** Data presented at the American Academy of Neurology (AAN) annual meeting add to the accumulating evidence of the positive benefit/risk profile of Gilenia, a potential first-in-class, once-daily oral therapy for relapsing forms of multiple sclerosis (MS).

Data from the two-year FREEDOMS study showed that Gilenia 0.5 mg reduced annual relapse rates (ARR) by 62% for treatment naïve patients compared to placebo. For patients previously receiving other treatments, the annual relapse rates were reduced by 44%. In addition, at two years Gilenia delayed the progression of disability by 30% for patients on 0.5 mg compared to placebo(1).

These findings reinforce the potential for Gilenia to be a breakthrough therapy option for physicians and people with relapsing forms of MS, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. The data demonstrate the effectiveness of Gilenia irrespective of treatment history, and further support both the sustained efficacy of Gilenia over two years and the potential benefits of switching from interferon beta-1a, a currently approved MS therapy, to Gilenia.

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Of the 1153 patients who participated in the one-year TRANSFORMS study, 1027 (89%) elected to enter the one-year extension study. Patients in the extension study who also received Gilenia in the core study remained on their original dose (0.5 mg or 1.25 mg), while patients who had received intramuscular interferon beta-1a (Avonex®) were randomized to receive Gilenia 0.5 mg or 1.25 mg(2).

Patients who received Gilenia 0.5 mg for two years experienced a consistently low ARR at year one (0.16) and at year two (0.18). These patients also retained a significant reduction in relapses and MRI brain lesions over two years compared to the group originally randomized to intramuscular interferon beta-1a and later switched to Gilenia(2).

In the subset of patients who received intramuscular interferon beta-1a during year one and Gilenia 0.5 mg during year two, the annual relapse rate in year two was reduced by 31% and the number of new or newly enlarged T2 lesions in the brain, a marker of disease activity, was reduced by 67% in the second year(2).

These findings on efficacy are consistent with those of the one-year core TRANSFORMS study demonstrating Gilenia significantly reduced annualized relapse rates by 52% (0.5 mg dose) vs. intramuscular interferon beta-1a(3).

Additional data presented at AAN showed that patients in the core TRANSFORMS study taking Gilenia 0.5 mg had a 71% reduction in relapses resulting in hospitalization, and a 52% reduction in relapses requiring steroid treatment compared with patients taking intramuscular interferon beta-1a(4).

The safety profile of Gilenia has been well studied in one of the largest-ever Phase III clinical trial programs conducted in MS. The full program, including completed as well as on-going studies in MS, now has more than 6600 patient years of experience, with some patients now in their sixth year of treatment.

In the TRANSFORMS and FREEDOMS studies the most commonly reported adverse events for both Gilenia and control groups were nasopharyngitis, headache and fatigue. Gilenia-related adverse events included transient, dose-related, generally asymptomatic heart rate reduction and infrequent transient AV conduction block at treatment initiation, mild (1-3 mm Hg) blood pressure increase, macular edema (more common with 1.25 mg than the 0.5 mg target dose), and asymptomatic, reversible elevation of liver enzymes.

The rates of infections overall, including serious infections, were comparable between treatment groups, although a slight increase in lung infections (primarily bronchitis) was seen in patients treated with Gilenia. The number of malignancies reported across the two studies was small with comparable rates between the Gilenia and control groups.

Novartis has submitted the 0.5 mg dose for regulatory approval in the US and EU as results from the studies indicate that this dose has the most favorable benefit/risk profile. Applications for regulatory approval for Gilenia 0.5 mg were submitted to the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) in December 2009. In February 2010, the FDA granted Gilenia priority review status. Since Gilenia involves a new active ingredient (New Molecular Entity), the FDA has required an Advisory Committee meeting on June 10 and will evaluate the risk management program, which could result in the FDA extending its review at the end of the designated six-month period in June 2010.

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(1) The brand name Gilenia has been provisionally approved by the FDA for use in connection with the product, but the product itself has not received marketing authorization or NDA approval from any regulatory authorities.

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The foregoing release contains forward-looking statements that can be identified by terminology such as potential, priority review, could, or similar expressions, or by express or implied discussions regarding potential marketing approvals for Gilenia, or the potential timing of such approvals, or regarding potential future revenues from Gilenia. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Gilenia to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Gilenia will be approved for sale in any market, or at any particular time. Nor can there be any guarantee that Gilenia will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Gilenia could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of

existing clinical data; competition in general; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, 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 provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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## References

- (1) Kappos L. et al. Oral Fingolimod (FTY720) vs Placebo in Relapsing Remitting Multiple Sclerosis: 24-month Clinical Efficacy Results from a Randomized, Double-Blind, Multicenter Phase III Study (FREEDOMS). Slide deck associated with Oral Presentation at the American Academy of Neurology (AAN) Annual Meeting 2010 in Toronto.
- (2) Khatri B. et al. 24-Month Efficacy and Safety Outcomes from the TRANSFORMS Extension Study of Oral Fingolimod (FTY720) in Patients with Relapsing-Remitting Multiple Sclerosis. Poster presented at AAN, Toronto, April 2010.
- (3) Cohen J. et al. Oral Fingolimod vs. Intramuscular Interferon in Relapsing Multiple Sclerosis. N Eng J Med 2010; 362:402-415.
- (4) Khatri B et al. Oral Fingolimod (FTY720) Reduces the Rate of Relapses that Require Steroid Intervention or Hospitalization Compared with Intramuscular Interferon  $\beta$ -1a: Results from a Phase III study (TRANSFORMS) in Multiple Sclerosis. Poster presented at AAN, Toronto, April 2010.

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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: April 13, 2010

By: /s/ MALCOLM B. CHEETHAM

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