

NOVARTIS AG  
Form 6-K  
April 12, 2011

# **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 11, 2011**

**(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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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:** ☒

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**Novartis International AG**

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**- Investor Relations Release -**

**Novartis therapy Gilenya™ reduced the risk of MS disability progression regardless of treatment history or disease severity, new analysis shows**

- *Gilenya delayed the progression of disability both for patients who were previously treated for their MS and for patients who had not received prior treatment*
- *11 scientific abstracts on Gilenya efficacy and safety will be presented at the American Academy of Neurology annual meeting*
- *Gilenya, first oral in a new class of drugs called S1P receptor modulators, is approved in more than 35 countries including US, Canada and Germany*

**Basel, April 11, 2011** A new analysis demonstrated that Gilenya (fingolimod) reduced the risk of disability progression in patients with relapsing-remitting multiple sclerosis (RRMS), regardless of treatment history. This analysis of the phase III two-year FREEDOMS study is one of 11 abstracts on Gilenya being presented at the 63rd annual meeting of the American Academy of Neurology (AAN).

In developing Gilenya, Novartis initiated a large clinical trial program that would provide the MS community with robust data to define the efficacy and safety profile of this oral treatment for relapsing forms of MS, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. Our scientific presence at AAN is evidence of our commitment to continued research and ongoing reporting of clinical information to physicians and patients.

The primary endpoint for the two-year FREEDOMS study was relapse rate, in which Gilenya reduced relapses by 54% compared to placebo ( $p < 0.001$ ). In a key secondary endpoint, Gilenya showed a 30% reduction ( $p < 0.05$ ) in the risk of 3-month confirmed disability progression as compared to placebo over two years.

The FREEDOMS analysis presented this week at AAN showed that 0.5 mg Gilenya-treated patients who were new to therapy ( $n = 493$ ) had a 37% reduction in the risk of 3-month confirmed disability progression compared to placebo (HR: 0.63; 95% CI: 0.41-0.95) while those previously treated with alternate therapies ( $n = 350$ ) Gilenya 0.5 mg led to a 30% reduction in risk (HR: 0.70; 95% CI: 0.43-1.14). Consistent favorable effects on disability progression were observed for Gilenya-treated patients compared to placebo for subgroups defined by age, gender, and disease severity as defined by EDSS score, relapse activity prior to study, magnetic resonance imaging (MRI) lesion burden or lesion

activity at the time of the start of the study.

These data provide deeper insights into the effect of Gilenya in significantly reducing MS disability progression across the broad range of patient subpopulations that this analysis evaluated, said Virginia Devonshire, MD Director of the University of British Columbia MS Clinic and a FREEDOMS trial investigator.

Gilenya, licensed from Mitsubishi Tanabe Pharma Corporation, is the first oral treatment in a new class of drugs called sphingosine 1-phosphate receptor (S1PR) modulators. Approved in more

than 35 countries including US, Canada and Germany, Gilenya has been studied in phase III clinical trials of over 2500 patients with relapsing-remitting MS. In MS, the immune system damages the myelin sheath that protects nerve fibers in the central nervous system (CNS), which includes the brain and spinal cord. As shown in animal models, Gilenya stops many of the white blood cells (lymphocytes) from leaving the lymph nodes. Exactly how Gilenya works in MS is unknown, but it is thought that it results in fewer white blood cells entering the CNS to attack and damage the myelin sheath. If Gilenya treatment is stopped for any reason, the number of white blood cells circulating in the body increases over the first few days and gradually returns to normal within 1 to 2 months.

The most common side effects are headache, liver enzyme elevations, influenza, diarrhea, back pain, and cough. Other Gilenya-related side effects include transient, generally asymptomatic, heart rate reduction and atrioventricular block upon treatment initiation, mild blood pressure increase, macular edema, and mild bronchoconstriction.

The rates of infections overall, including serious infections, were comparable among treatment groups, although a slight increase in lower respiratory tract infections (primarily bronchitis) was seen in patients treated with Gilenya. The number of malignancies reported across the clinical trial program was small, with comparable rates between the Gilenya and control groups.

#### **About Multiple Sclerosis**

While there is still much to be understood about multiple sclerosis, it is thought to be an autoimmune disease of the central nervous system that is chronic, progressive and often disabling. It affects over 400,000 Americans and more than 2.1 million people worldwide. The most common forms of the disease, relapsing forms of MS, are characterized by exacerbations or flare-ups interspersed with periods of disease remission. Typically, MS strikes in early adulthood between the ages of 20 and 50 and affects women twice as frequently as men.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, will, would, commitment, or similar expressions, or by express or implied discussions regarding potential future indications or labeling for Gilenya, or regarding potential future revenues from Gilenya. 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 Gilenya to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Gilenya will be submitted or approved for any additional indications or labeling. Nor can there be any guarantee that Gilenya will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Gilenya could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; government, industry and general public pricing pressures, including governmental reimbursement issues; competition in general; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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.

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 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates (including 16,700 Alcon associates) and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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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 11, 2011

By: /s/ MALCOLM B. CHEETHAM

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