

NOVARTIS AG  
Form 6-K  
January 24, 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 January 21, 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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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 gains positive CHMP opinion for Gilenya®, first oral multiple sclerosis treatment recommended for approval in the European Union**

- *Gilenya recommended in the EU for people with highly active relapsing-remitting MS despite treatment with beta interferon, or in patients with rapidly evolving severe relapsing-remitting MS*
- *Gilenya showed superior efficacy to interferon beta-1a IM, a commonly prescribed treatment, reducing relapses by 52% ( $p < 0.001$ ) at one year*
- *Two-year, placebo-controlled study demonstrated that Gilenya significantly reduced the risk of disability progression*

**Basel, January 21, 2011** The European Medicines Agency Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Gilenya® (fingolimod) 0.5 mg daily as a disease modifying therapy in patients with highly active relapsing-remitting multiple sclerosis (MS) despite treatment with beta interferon, or in patients with rapidly evolving severe relapsing-remitting MS.

The CHMP opinion was based on the largest clinical trial program submitted to date for a new MS drug, and included data from clinical studies showing significant efficacy in reducing relapses, the risk of disability progression, and the number of brain lesions detected by magnetic resonance imaging (MRI), a measure of disease activity(1),(2).

More than 500,000 people in the EU live with MS, a debilitating neurological condition that involves an unpredictable, life-long progression of complex symptoms, commented John Golding, President, European Multiple Sclerosis Platform (EMSP). The first available oral MS treatment that offers significant efficacy for appropriate patients is a welcome alternative.

The CHMP recommendation forms the basis for a European Commission licensing decision, which is expected in approximately three months.

We're pleased with today's recommendation by the CHMP because it means patients in Europe with highly active relapsing-remitting MS could soon benefit from Gilenya's significant efficacy in a once-daily capsule," said David Epstein, Division Head of Novartis Pharmaceuticals.

Novartis is committed to providing innovative medicines like Gilenya to patients with multiple sclerosis, and we look forward to working with countries across Europe towards this goal.

#### **About Gilenya**

Gilenya, licensed from Mitsubishi Tanabe Pharma Corporation, is the first in a new class of drugs called sphingosine 1-phosphate receptor (S1PR) modulators. In MS, the immune system damages the covering that protects nerve fibers in the central nervous system (CNS), which includes the brain and spinal cord. The novel mechanism of Gilenya is thought to work by

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reducing the immune system's attack on the CNS by retaining certain white blood cells (lymphocytes) in the lymph nodes. This prevents the white blood cells from reaching the CNS, where they could potentially attack the protective covering around the nerve fibers, resulting in less inflammatory damage to the nerve cells. The white blood cell retention is reversible if Gilenya treatment is stopped.

The EU application included data showing Gilenya 0.5 mg reduced relapses by 52% ( $P < 0.001$ ) at one year compared with interferon beta-1a IM (Avonex®), one of the most commonly prescribed treatments for MS. Data from a two-year placebo-controlled study showed a reduction in the risk of disability progression among Gilenya patients (30% reduction confirmed at three-month follow-up visit  $P = 0.02$ , compared with placebo)(2). In clinical studies, treatment with Gilenya also resulted in statistically significant reductions in brain lesion activity as measured by MRI.

Gilenya has been studied in more than 4000 MS patients. 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.(1),(2)

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.(1),(2)

Avonex® is a registered trademark of Biogen Idec.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as recommended, recommendation, expected, could, committed, look forward, potentially, or similar expressions, or by express or implied discussions regarding potential additional marketing for Gilenya, or regarding the timing of any such approvals, 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 approved for sale in any additional markets, or at any particular time. 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; 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 102,000 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) Cohen et al. Oral Fingolimod vs. Intramuscular Interferon in Relapsing Multiple Sclerosis. *N Engl J Med*. Vol.362 No.5, Feb 4, 2010 (printed version)

(2) Kappos L, et al. Placebo-Controlled Study of Oral Fingolimod in Relapsing Multiple Sclerosis. *N Eng J Med*. Vol.362 No.5, Feb 4, 2010 (printed version).

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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: January 21, 2011

By:

/s/ MALCOLM B. CHEETHAM

Name:

Malcolm B. Cheetham

Title:

Head Group Financial Reporting and Accounting

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