NOVARTIS AG
Form 6-K
March 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 March 21, 2011

(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):

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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: o **No**: **x**

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- Investor Relations Release -

Novartis receives European Commission approval for Gilenya®, the first oral multiple sclerosis treatment for use in the EU

- *Gilenya approved in the EU for people with highly active relapsing-remitting multiple sclerosis (RRMS) despite treatment with beta interferon, or in patients with rapidly evolving severe RRMS*

- *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, March 21, 2011 The European Commission has granted Novartis approval for Gilenya® (fingolimod) 0.5 mg daily as a disease modifying therapy in patients with highly active relapsing-remitting multiple sclerosis (RRMS) despite treatment with beta interferon, or in patients with rapidly evolving severe RRMS.

Today marks an important step forward in the way we manage this chronic, debilitating disease in Europe, said Professor Hans-Peter Hartung, Professor and Chairman, Dept. of Neurology, Heinrich-Heine University, Germany. Gilenya is the first approved therapy for MS that offers significant efficacy in a capsule, which for many patients will come as a welcome additional option.

The approval 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).

Today s announcement marks another major regulatory approval and we are pleased that Gilenya will become available to more eligible MS patients, said David Epstein, Division Head of Novartis Pharmaceuticals. Novartis is dedicated to bringing innovative new treatments to patients where there is significant unmet need. Gilenya has been in clinical development for MS since 2003 and we are grateful for the commitment of those involved, especially the trial participants, who have contributed significantly to the development of this novel medicine.

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 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 will, dedicated, commitment, potentially, or similar expressions, or by express or implied discussions regarding the timing of the launch of Gilenya in Europe, 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 launched in any particular European country 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; 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.

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:	March 21, 2011	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting