NOVARTIS AG
Form 6-K
January 25, 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 24, 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):

Yes: o **No**: x

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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

Novartis International AG

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- Investor Relations Release -

Novartis gains approval for Gilenya® as a first-line disease modifying oral therapy for multiple sclerosis in Switzerland and Australia

- *Gilenya offers an alternative to frequent injections, which is a major advance for people with relapsing-remitting multiple sclerosis in Switzerland and Australia*

- *Gilenya showed enhanced 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 24, 2011 Swissmedic, the Swiss Agency for Therapeutic Products, and the Australian Therapeutic Goods Administration (TGA) have granted approval for Gilenya® (fingolimod) 0.5 mg as a first-line, oral disease-modifying therapy (DMT) for the treatment of relapsing-remitting multiple sclerosis (RRMS).

Gilenya, with its innovative mechanism of action, can improve clinical outcomes in patients with relapsing remitting MS, said Professor Ludwig Kappos, Neurology and Department of Research, University Hospital, Basel, Switzerland. The significant efficacy and manageable safety profile of Gilenya make it a valuable new option for patients with relapsing-remitting MS and the physicians who treat them.

The Gilenya approvals were based on the largest clinical trial program conducted in MSto date(1),(2). The application included data showing Gilenya 0.5 mg reduced relapses by 52% (*P*<0.001) at one year compared with interferon beta-1a IM, an approved first-line DMT(1). Data from a two-year placebo-controlled study showed a reduction in relapse rate of 54% (*P*<0.001) compared with placebo*(2)*. In the same study, patients on Gilenya 0.5 mg had a 30% lower risk of disability progression, confirmed after three months and a 37% lower risk of disability progression, confirmed after six months(2).

The studies also showed that treatment with Gilenya resulted in statistically significant reductions in brain lesion activity as measured by magnetic resonance imaging.

Following the approval of Gilenya in the United States and in Russia, we are proud that we can now offer this effective, once-daily oral treatment to patients in Switzerland and Australia, said David Epstein, Division Head of Novartis Pharmaceuticals. Novartis has an excellent track record of securing access to innovative medicines for patients and we are committed to assuring access to Gilenya for eligible patients around the world.

Gilenya, licensed from Mitsubishi Tanabe Pharma Corporation, is the first in a new class of compounds called sphingosine 1-phosphate receptor (S1PR) modulators. Gilenya provides

selective and reversible retention of lymphocytes in lymph nodes, which helps preserve key immune functions and provides flexibility in patient management.

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 Gilenya-treated patients. The number of malignancies reported across the clinical trial program was small, with comparable rates between the Gilenya and control groups.(1),(2)

Multiple Sclerosis can cause a range of physical and mental problems including loss of muscle control and strength, vision, balance, sensation and mental function. Over time, with repeated attacks, damage accumulates leading to permanent nerve damage and loss of neurological function. It is estimated that MS affects up to 2.5 million people worldwide(3) and is potentially the most common cause of non-traumatic, neurological disability in young adults.

Novartis has filed Gilenya with health authorities worldwide.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as can, committed, potentially, or similar expressions, or by express or implied discussions regarding potential approvals to market Gilenya in additional countries, or the timing of 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 market, 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 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.

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).

(3) Multiple Sclerosis International Federation. Atlas of MS [online]. Available at: www.atlasofms.org. Accessed December 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: January 24, 2011

By: /s/ MALCOLM B. CHEETHAM

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