NOVARTIS AG
Form 6-K
April 20, 2012

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 20, 2012

(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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Yes: o **No**: x

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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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis updates US label on Gilenya® following discussions with the FDA

- *Updated Gilenya label provides further guidance to healthcare providers regarding treatment initiation with Gilenya in MS patients in the United States*

- *Prescribing information includes patient selection parameters to aid in the identification of candidates for Gilenya treatment*

- *Update to label marks the conclusion of discussions initiated in December 2011*

Basel, April 20, 2012 Novartis announced today agreement with the US Food and Drug Administration (FDA) on label changes for Gilenya® (fingolimod).

The update to the Gilenya prescribing information includes patient selection parameters to aid in the identification of candidates for Gilenya treatment and more specific recommendations for treatment initiation for patients with relapsing forms of MS in the United States. The update marks the conclusion of discussions initiated in December 2011.

The updated FDA label for Gilenya indicates that all patients initiating treatment with Gilenya should have an electrocardiogram (ECG) prior to the first dose of the medicine and after the six-hour first-dose observation period in addition to hourly measurement of blood pressure and heart rate. Additionally, specific initiation guidance for patients is now provided to better aid healthcare providers. Further, there are revised recommendations on how to re-initiate therapy should Gilenya be interrupted.

As of February 2012, approximately 36,000 patients have been treated with Gilenya in clinical trials and in the post-marketing setting.

Gilenya represents an important treatment option for relapsing forms of MS, said Dr. Barry Singer, Director, MS Center for Innovations in Care, Missouri Baptist Medical Center. Choosing appropriate patients for Gilenya therapy and patient safety is essential.

If therapy is interrupted for patients who are already taking Gilenya, they should undergo the new recommended monitoring upon treatment re-initiation as per the revised recommendations on the duration of interruption depending on duration of prior treatment. Patients should not make any changes to any medications they are taking, including Gilenya, without consulting their doctor.

The label update in the US for Gilenya recommends that patients with certain pre-existing cardiac conditions or those taking certain concomitant medications would require overnight monitoring following administration of first dose of medication, and for some patients prior evaluation with a specialist. Experience with the use of Gilenya in such patients was limited in the pivotal clinical trials.

Gilenya is contraindicated in patients with history or presence of certain cardiac conditions, including heart attack or stroke in the past six months, second- and third-degree AV block and other serious cardiac rhythm disturbances, and in patients treated with certain anti-arrhythmic drugs.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as recommendations, believe, recommends, or similar expressions, or by express or implied discussions 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 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, including the finalization of EU review of the Gilenya label; 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; unexpected manufacturing issues; 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 innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group s continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 124,000 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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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 20, 2012

By: /s/ MALCOLM B. CHEETHAM

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