

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:

Edgar Filing: NOVARTIS AG - Form 6-K

**Form 20-F:**  **Form 40-F:**

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:  No:

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes:  No:

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:

---

**Novartis International AG**  
Novartis Global Communications  
CH-4002 Basel  
Switzerland  
<http://www.novartis.com>

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

**Novartis confirms positive benefit-risk profile of Gilenya® following CHMP review and label update recommendation**

- *Revised label agreed between Novartis and the CHMP provides further guidance to healthcare providers regarding treatment initiation with Gilenya in MS patients in the EU*
- *Patients should have ECG before and six hours after the first-dose, with hourly blood pressure and heart rate measures; Continuous ECG recommended*
- *Caution regarding use in patients who may be less tolerant of or are more likely to develop significantly slowed or abnormal heart rate*

**Basel, April 20, 2012** Novartis announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has confirmed a positive benefit-risk profile of once-daily oral Gilenya® (fingolimod). Novartis and the CHMP have agreed to recommended updates to the product information in the European Union in order to provide further guidance to healthcare providers regarding treatment initiation with Gilenya in MS patients. The changes follow the Article 20 review by the EMA announced in January 2012.

In the European Union, all MS patients initiating treatment with Gilenya should have an electrocardiogram (ECG) and a blood pressure measurement prior to the first dose of the medicine and after the six-hour first-dose monitoring period. Blood pressure and heart rate should be measured every hour during this period, and continuous ECG monitoring is recommended for a minimum of six hours following the first dose.

We believe that Gilenya is a valuable treatment option for many patients with relapsing remitting MS, and we welcome the confirmation of the positive benefit-risk profile of the drug which also supports our continued belief of the blockbuster potential of Gilenya, said David Epstein, Division Head of Novartis Pharmaceuticals. MS is a devastating chronic disease that affects more than 2.1 million people worldwide, and patients need effective treatment options.

As of February 2012, approximately 36,000 patients have been treated with fingolimod in clinical trials and in the post-marketing setting, some up to seven years, and currently there is approximately 34,000 patient years of exposure. In the European Union, Gilenya is approved for people with highly active relapsing-remitting MS despite treatment with beta interferon, or in patients with rapidly evolving severe relapsing-remitting MS.

**More about the CHMP recommended label update**

Extended ECG monitoring is required after first-dose of Gilenya for patients who have very low or their lowest measured heart rate at the six hour time point, and in patients who have symptomatic bradycardia (low heart rate) or ECG abnormalities at any time during the six hour monitoring.

In addition, the recommended label update in the European Union cautions against use in patients who may be less tolerant of or are more likely to develop significantly slowed

or abnormal heart rate because of certain underlying conditions or concomitant medications. If treated, these patients would require overnight monitoring. Experience with the use of Gilenya in such patients was limited in the pivotal clinical trials.

The new first-dose observation recommendations do not affect patients who are already taking Gilenya. If therapy is interrupted for more than two weeks, patients should undergo the new recommended monitoring upon treatment re-initiation. Patients should not make any changes to any medications they are taking, including Gilenya, without consulting their doctor.

The CHMP labeling recommendations will be reviewed by the European Commission with a final decision expected in June 2012. Novartis will inform physicians in the European Union of the changes in the product information in the EU via a Direct Healthcare Provider Communication (DHPC) by end of April 2012.

#### **About Gilenya® (fingolimod)**

Gilenya, licensed from Mitsubishi Tanabe Pharma Corporation, is the first in a new class of compounds called sphingosine 1-phosphate receptor (S1PR) modulators. It has demonstrated superior efficacy compared to Avonex® (interferon-beta-1a IM), a commonly prescribed treatment, showing a 52% relative reduction in annualized relapse rate (primary endpoint) and a 40% relative reduction in the rate of brain atrophy (secondary endpoint) at one year in a pivotal head-to-head trial in patients with relapsing-remitting multiple sclerosis. In a recent sub-analysis, Gilenya showed a 61% relative reduction in annualized relapse rate compared to interferon-beta-1a (IM) at one year in subgroups of patients with highly active relapsing-remitting MS patients previously treated with interferon.

Gilenya is generally a highly effective once-daily oral MS treatment without label restrictions specific to treatment duration. In clinical trials it was generally well tolerated with a manageable safety profile, and there is increasing experience of Gilenya's long-term effectiveness and safety profile, with more than 36,000 patients having been treated as of February 2012 in clinical trials and in the post-marketing setting, 2,400 patients having been on treatment for more than two years. In clinical trials, the most common side effects were headache, liver enzyme elevations, influenza, diarrhea, back pain, and cough. Other Gilenya-related side effects included 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.

As part of the Novartis commitment to transparency, the Gilenya Information Center has recently launched. For more information please visit the Gilenya information site at <http://www.novartis.com/newsroom/product-related-info-center/gilenya.shtml>.

#### **Note to investors**

## Edgar Filing: NOVARTIS AG - Form 6-K

Novartis has scheduled a conference call with members of the financial community to discuss this announcement on Friday, April 20, at 15:00 Central European Time. A simultaneous live webcast may be accessed by visiting the Novartis website at [www.novartis.com](http://www.novartis.com).

### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as recommendation, should, recommended, potential, will, recommendations, expected, or similar expressions, or by express or implied

discussions regarding potential new 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 approved for any additional labeling in any 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, including the finalization of the EU review of the CHMP labeling recommendations; 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>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>.

###

#### **Novartis Media Relations**

**Central media line :** +41 61 324 2200

**Eric Althoff**

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

[eric.althoff@novartis.com](mailto:eric.althoff@novartis.com)

**Julie Morrow**

Novartis Pharma Communications

+41 61 696 7581 (direct)

+41 79 357 3259 (mobile)

[julie.morrow@novartis.com](mailto:julie.morrow@novartis.com)

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

Edgar Filing: NOVARTIS AG - Form 6-K

For Novartis multimedia content, please visit [www.thenewsmarket.com/Novartis](http://www.thenewsmarket.com/Novartis)  
For questions about the site or required registration, please contact: [journalisthelp@thenewsmarket.com](mailto:journalisthelp@thenewsmarket.com).



**Novartis Investor Relations**

**Central phone:** +41 61 324 7944  
Susanne Schaffert +41 61 324 7944  
Pierre-Michel Bringer +41 61 324 1065  
Thomas Hungerbuehler +41 61 324 8425  
Isabella Zinck +41 61 324 7188

**North America:**  
Helen Boudreau +1 212 830 2404  
Jill Pozarek +1 212 830 2445  
Edwin Valeriano +1 212 830 2456

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

**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