NOVARTIS AG
Form 6-K
June 11, 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 June 11, 2012**

**(Commission File No. 1-15024)**

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# Novartis AG

(Name of Registrant)

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**MEDIA RELEASE • MEDIA RELEASE • MEDIA RELEASE**

**Novartis drug Gilenya® shows long-term efficacy and safety according to new data from extension of phase III head-to-head study**

- *Data from single-arm extension of head-to-head TRANSFORMS study show sustained reduction in relapses and rate of brain volume loss in patients on continuous Gilenya treatment for up to 4.5 years*

- *Reductions in relapses and MRI measures were observed in patients who switched from Avonex® (interferon-beta-1a IM) to Gilenya for study extension phase*

- *Extension study results demonstrated once-daily oral Gilenya was generally well-tolerated with a safety profile consistent with pivotal trials*

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

**Basel, June 11, 2012** New long-term data for Gilenya® (fingolimod), the only oral therapy approved to treat people with relapsing forms of multiple sclerosis (MS), show a sustained efficacy benefit and a consistent safety profile with up to 4.5 years of continuous treatment(1). These results, from an extension of the phase III head-to-head TRANSFORMS study, also showed improved efficacy for patients switched to Gilenya from Avonex® (interferon-beta-1a IM), a commonly prescribed MS treatment(1).

These data further reinforce our confidence in Gilenya s long-term effectiveness and safety profile The TRANSFORMS extension study shows that MS patients treated continuously with Gilenya for up to four and a half years demonstrated sustained low levels of clinical and MRI activity, said Tim Wright, Global Head of Development, Novartis Pharma. Furthermore, patients who switched to Gilenya from interferon beta-1a IM showed a reduction in relapses and improvements in MRI measures in the extension compared to the core study.

In the core TRANSFORMS study, Gilenya demonstrated superior efficacy to interferon-beta- 1a IM, reducing the annualized relapse rate (ARR) by 52% at one year (Gilenya 0.5 mg, ARR = 0.16; interferon-beta- 1a IM, ARR = 0.33; $p<0.001$)(2). The extension study showed that this low relapse rate was sustained in patients receiving continuous treatment with Gilenya (n=356) for up to 4.5 years (Gilenya 0.5 mg, ARR core study = 0.16; ARR extension study = 0.16). The data from the extension study also showed that patients treated with Gilenya continuously maintained a low brain atrophy rate throughout the study as measured by assessing brain volume loss, which is valued as a predictor of long-term

disability(1).

For patients who switched to Gilenya for the open-label extension study (n=167), their ARR was 0.33 in the core study when treated with interferon-beta-1a IM and 0.20 in the extension phase when treated with Gilenya (n.s.). Patients in the switch group also displayed a slowing of brain atrophy following the switch to Gilenya(1),(2).

These extension data from up to 4.5 years also showed long-term treatment with Gilenya was generally well tolerated with a safety profile consistent with pivotal trials. In line with

previous studies, including the core TRANSFORMS study, the most common adverse events were nasopharyngitis, headache, and upper respiratory tract infections(2),(3). Switching therapy from IFN beta-1a to Gilenya did not reveal any new or unexpected safety concerns. On treatment initiation, a low incidence of asymptomatic transient bradycardia was observed in patients who switched from interferon-beta-1a IM to Gilenya (IFN-0.5 mg [0.6%]), which resolved without treatment. Overall cardiac events were similar across all patient groups(3).

In addition, all patients treated with Gilenya in the extension phase, regardless of original treatment in the core study, showed comparable percentage of patients free from MRI disease activity by the end of the study. (Free from Gd enhanced T1 lesions: 77.4% in switch group vs. 74.7% Gilenya 0.5mg; Free from new/newly enlarged T2 lesions: 45.0% in switch group vs. 42.0% Gilenya 0.5mg). The continuous and switch groups did not significantly differ with respect to disability progression at the end of the study(1).

This extension study data provide deeper insight into the efficacy and safety profile of fingolimod, said Dr. Xavier Montalban, Director of the Multiple Sclerosis Center of Catalonia and of the Unit of Clinical Neuroimmunology, Vall d´Hebron University Hospital, Barcelona, Spain. The results, which are consistent with the pivotal phase III studies, confirm that fingolimod is highly effective in treating relapsing forms of MS, and as the first available oral MS treatment, continues to be a valuable treatment option for appropriate patients.

TRANSFORMS was a large phase III double-blind, double-dummy, head-to-head study that involved 1,292 patients with relapsing-remitting MS that was conducted over one year, comparing the efficacy and safety of Gilenya to interferon-beta-1a IM(2). At the end of the 12-month core study, eligible patients could enroll in the extension study, which ran for an additional 3.5 years. Patients on once-daily oral Gilenya remained on drug and those who had been treated with interferon-beta-1a (IM) switched to Gilenya for the duration of the extension study(1).

These data were presented at the 22nd Annual Meeting of the European Neurological Society (ENS), taking place 9-12 June 2012 in Prague, Czech Republic.

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.

**About Gilenya**

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, 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(2). 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 not responding to interferon treatment(4).

Gilenya is generally a highly effective once-daily oral MS treatment. 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 approximately 36,000 patients having been treated in clinical trials and in a post-marketing setting(5). Currently, there is approximately 34,000 patient years of exposure. 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(2),(5),(6).

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(2),(6).

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as confidence, or similar expressions, or by express or implied discussions regarding potential new indications or 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 submitted or approved for any additional indications or 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; 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.

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**References:**

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(2) Cohen J. et al. Oral Fingolimod vs. Intramuscular Interferon in Relapsing Multiple Sclerosis. *N Eng J Med.* Vol.362 No.5, Feb 4, 2010;362:402-415.

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Prague, June 2012.

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(6) 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; 362:387-401.

Avonex® is a registered trademark of Biogen Idec.

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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**

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| Date: | June 11, 2012 | By: | /s/ MALCOLM B. CHEETHAM |
| | | Name: | Malcolm B. Cheetham |
| | | Title: | Head Group Financial Reporting and Accounting |