

NOVARTIS AG  
Form 6-K  
October 18, 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 October 17, 2011**

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

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(Name of Registrant)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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Yes:  No:

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**- Investor Relations Release -**

**Novartis drug Gilenya® (fingolimod) has more than 20,000 patient-years of exposure and shows up to 71% reduction in annualized relapse rates in MS patients with highly active disease**

- *Analyses presented at 5th Joint Triennial Congress ofECTRIMS and ACTRIMS showed relapse rate reductions were consistent among subgroups of fingolimod-treated patients that had highly active disease in pivotal clinical trials*
- *Fingolimod demonstrated reductions in rates of brain atrophy compared to interferon beta-1a IM regardless of disease activity*
- *To date, approximately 25,000 patients treated with fingolimod and more than 20,000 patient-years of exposure; more than 20,000 patients on commercial drug*

**Basel, October 17, 2011** Novartis will showcase data from 13 abstracts on fingolimod (Gilenya®), at the 5th Joint Triennial Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) taking place from 19-22 October in Amsterdam.

The data being presented for fingolimod at ECTRIMS/ACTRIMS highlight the Novartis clinical trial program for sphingosine 1-phosphate receptor (S1PR) modulators. Fingolimod targets MS via effects on the immune system and new pre-clinical data to be presented at ECTRIMS/ACTRIMS supports an additional potential direct effect on the central nervous system (CNS)(1),(2), although the clinical relevance of this remains to be determined. Additional clinical data describe efficacy in subgroups of patients with highly active disease in the pivotal Phase III studies.

Gilenya has already demonstrated significant efficacy in large scale clinical trials which is reinforced by these important data presented at ECTRIMS/ACTRIMS reflecting different patient populations in need of a new treatment, said David Epstein, Head of the Pharmaceuticals Division at Novartis Pharma AG. These findings will help further solidify the role of Gilenya in the treatment of MS within its approved indication.

Data highlights include:

Fingolimod 0.5 mg significantly reduced annualized relapse rates (ARR) by up to 71% (from 61% to 71%) compared to interferon beta-1a IM and compared to placebo in relapsing-remitting multiple sclerosis (MS) patients with high disease activity despite previous MS disease-modifying treatment. Although the reduction in ARR in another subgroup of patients, those patients with rapidly evolving severe relapsing-remitting MS, was directionally consistent with other subgroup data, statistical significance was not achieved compared to interferon beta-1a IM due to the small number of patients in this subgroup(3). (Abstract P473)

- In relapsing-remitting MS patients with high disease activity despite previous MS disease-modifying treatment, the relative reduction of ARR ranged from 61% compared to interferon beta-1a in TRANSFORMS to 62%-71% compared to placebo in FREEDOMS.
- In the European Union, Gilenya 0.5 mg is approved for the treatment of relapsing-remitting MS in patients with high disease activity despite treatment with interferon beta, and in patients with rapidly evolving severe relapsing-remitting MS.

Fingolimod 0.5 mg reduced the rate of brain atrophy, or brain volume loss, compared to interferon beta 1a IM over 12 months, irrespective of disease activity prior to study start as shown in an analysis of the pivotal Phase III TRANSFORMS study. (Abstract P907)

A five year Phase II study extension showed that patients with relapsing MS treated with fingolimod maintained low disease activity with a safety profile consistent with that seen in other fingolimod clinical trials. Of the original 281 patients at the start of the Phase II study, approximately 50% (140 patients) completed five years of treatment(4). (Abstract P978)

In addition to the data presentations, onsite at the RAI Exhibition and Conference Centre there will be a Novartis symposium, Fingolimod: pioneering innovation in MS treatment, taking place on Friday 21st October, 12:45 – 13:45 CET. There will also be three interactive MS Innovation Exchanges, including two on October 20 and one on October 21. The MS Innovation Exchanges are an opportunity for healthcare professionals to learn about innovations in patient care, neuroimaging and patient outcomes. Healthcare professionals should visit the Novartis booth for more information. In addition, a press briefing will be taking place on Friday, October 21 from 15:30-17:00 CET.

#### **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(5).

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 25,000 patients having been treated as of mid October 2011 in clinical trials and in a post-marketing setting. Currently, there is more than 20,000 patient years of exposure(6). 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(5),(7).

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(5),(7).

The following key Novartis data will be presented during theECTRIMS/ACTRIMS congress:

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1. Abstract P473: Clinical and magnetic resonance imaging outcomes in subgroups of patients with highly active relapsing-remitting multiple sclerosis treated with fingolimod (FTY720): results from the FREEDOMS and TRANSFORMS phase 3 studies
2. Abstract P907: Fingolimod (FTY720) reduces brain volume loss over 12 months compared with intramuscular interferon beta-1a: subgroup analyses of TRANSFORMS data based on inflammatory disease activity

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3. Abstract P320: A controlled study on the effect of fingolimod (FTY720) on the immune response following seasonal influenza vaccination and tetanus toxoid booster injection in patients with Multiple Sclerosis
4. Abstract P369: Brain distribution of BZM055, an imaging analog of fingolimod (FTY720), in non-human primate
5. Abstract P978: Long-term fingolimod (FTY720) in relapsing MS: 5-year results from an extension of a phase II, multicenter study show a sustained low level of disease activity
6. Abstract P239: Effect of fingolimod (FTY720) on disability progression: Application of a transition model to EDSS data collected in the FREEDOMS and TRANSFORMS trials
7. Abstract P494: Fingolimod (FTY720) modulates microglial activation to augment markers of remyelination
8. Abstract P930: Oral fingolimod (FTY720) in Japanese patients with relapsing multiple sclerosis: results of a 6-month, randomized, double-blind, placebo-controlled, phase 2 study
9. Abstract P460: Oral fingolimod (FTY720) in Japanese patients with relapsing multiple sclerosis: Results of a 12-month, phase 2 extension study
10. Abstract P961: Nervous system and immune system effects of sphingosine 1-phosphate receptor 5 deletion in mice alters experimental autoimmune encephalitis progression and the efficacy of fingolimod
11. Abstract P552: Treatment experience, burden and unmet needs (TRIBUNE) in multiple sclerosis study: patient preferences for MS treatments
12. Abstract P767: T-Cell response against varicella zoster virus in fingolimod treated patients with multiple sclerosis
13. Abstract P823: Sphingosine 1-phosphate receptor antagonists promote axonal ensheathment by human fetal oligodendrocyte progenitors

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as will, to be presented, potential, 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. 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 clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; unexpected product 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 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, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. 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 121,000 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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## References

- (1) Tamagnan G. et al. Brain distribution of BZM055, an imaging analog of fingolimod (FTY720), in non-human primate. Data Presented at ECTRIMS, Amsterdam, October 2011.
- (2) Noguchi K. et al. Nervous system and immune system effects of sphingosine 1-phosphate receptor 5 deletion in mice alters experimental autoimmune encephalitis progression and the efficacy of fingolimod. Data Presented at ECTRIMS, Amsterdam, October 2011.
- (3) Havrdová E et al. Clinical and magnetic resonance imaging outcomes in subgroups of patients with highly active relapsing-remitting multiple sclerosis treated with fingolimod (FTY720): results from the FREEDOMS and TRANSFORMS phase 3 studies. Data Presented at ECTRIMS, Amsterdam, October 2011.
- (4) Montalban X et al. Long-term fingolimod (FTY720) in relapsing MS: 5-year results from an extension of a phase II, multicenter study show a sustained low level of disease activity. Data Presented at ECTRIMS, Amsterdam, October 2011.
- (5) Cohen J. et al. Oral Fingolimod vs. Intramuscular Interferon in Relapsing Multiple Sclerosis. *N Eng J Med.* 2010; 362:402-415.
- (6) Novartis data on file.
- (7) Kappos L, et al. Placebo-Controlled Study of Oral Fingolimod in Relapsing Multiple Sclerosis. *N Eng J Med.* 2010; 362:387-401.

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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: **October 17, 2011**

By: */s/ MALCOLM B. CHEETHAM*

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