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FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

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THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated December 15, 2011

(Commission File No. 1-15024)

Novartis AG

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- Investor Relations Release -

Novartis drug Gilenya® showed positive clinical outcomes for relapsing-remitting MS patients in third large Phase III clinical trial

- *Once-daily oral MS medicine showed a 48% relative reduction in annualized relapse rate, meeting primary endpoint in Phase III placebo-controlled study*

- *Significant reduction in brain volume loss demonstrated, reinforcing strong efficacy benefit in key secondary endpoint*

- *Safety and tolerability were broadly consistent with previous clinical trials*

Basel, December 15, 2011 Novartis announced today new data from the Phase III 2309 study showing patients with relapsing-remitting multiple sclerosis (RRMS) treated with Gilenya® (fingolimod) had a statistically significant 48% reduction in annualized relapse rates (ARR) at 24 months compared to placebo. Study 2309 is the third Phase III clinical trial to demonstrate a significant reduction of relapse rates with Gilenya treatment in patients with RRMS. The two previous Gilenya studies involved a two-year, placebo-controlled trial and a one-year, head-to-head trial against interferon-beta-1a (IM) in which the once-daily oral medicine showed a 54% and a 52% relative reduction in ARR, respectively(1),(2).

A reduction of brain volume loss, a pre-defined key secondary endpoint for study 2309, also achieved statistical significance for Gilenya-treated patients compared to placebo. Brain volume loss is valued as a predictor of long-term disability(3) and study 2309 is the third Phase III clinical trial where Gilenya demonstrated high efficacy in this MRI (magnetic resonance imaging) measure compared to control.

Study 2309 confirms the efficacy of Gilenya across several key measures, including reductions in annualized relapse rate and reductions in brain volume loss, said David Epstein, Head of the Pharmaceuticals Division at Novartis Pharma AG. With more than 20,000 patient years of fingolimod exposure to date, Gilenya continues to demonstrate its value to patients and the MS community. We are looking forward to presenting the full data to the clinical community at a scientific congress next year.

Gilenya-treated patients had a 17% and 28% reduction in three-month and six-month confirmed disability progression, compared to placebo as measured by EDSS (expanded disability status scale), respectively, which were not statistically significant. A post-hoc analysis of the data showed that this result is likely due to a high variability in EDSS measurements among patients with low baseline scores (i.e. 0.0 and 1.0).

A subsequent analysis that applied a more rigorous definition of EDSS disability progression reduced the impact of this variability. Specifically, Gilenya-treated patients showed approximately a 34% reduction of six-month confirmed disability progression compared to placebo when a 1.5 point increase in EDSS was used to define progression in patients with baseline EDSS scores of zero, rather than the pre-specified 1.0 point increase. This disability reduction outcome is in range with what was seen in previous clinical trials. Further, study 2309 showed a statistically significant difference from placebo in the Multiple Sclerosis Functional Composite (MSFC), an alternative disability scale pre-defined in the clinical trial.

The results of this third Phase III study of Gilenya confirm data from the previous two studies that this drug is highly effective in relapsing forms of MS, said Peter Calabresi, M.D., Professor of Neurology, Johns Hopkins University. The absence of an effect on disability in this trial is in contrast to the previous placebo comparison trial and seems to relate to inaccuracies of the EDSS scale at the low end where there is known to be quite a bit of variability. Nonetheless, there was a reduction of disability in line with previous trials if one employs a more rigorous definition of change, which is in keeping with the observed reduction in brain atrophy as well as other functional outcome measures of disease progression.

Safety and tolerability were broadly consistent with the safety profile of fingolimod as characterized in the previous Phase III clinical trials. There were no deaths in fingolimod treated patients in the trial. Symptomatic bradycardia and associated AV-conduction blocks were rare and none required symptomatic treatment at the fingolimod 0.5 mg dose. As in previous studies, other adverse events which were observed more frequently in fingolimod-treated patients included liver transaminase elevations, hypertension and lymphopenia.

The overall rate of infections was similar between fingolimod- and placebo-treated patients. Although herpes viral infections were reported more frequently with fingolimod in this trial, updated integrated analyses of all controlled clinical trials from the fingolimod development program show no differences in the incidence of herpes viral infections between fingolimod and placebo treatment groups. Malignancies were equally distributed across treatment groups in this study with the exception of basal cell carcinomas of the skin which, although of low incidence, were more frequently reported in fingolimod treated patients.

Study 2309 was a two-year placebo-controlled, parallel-group, multi-center Phase III clinical trial evaluating the efficacy and safety of Gilenya (fingolimod) 0.5 mg in patients with relapsing-remitting multiple sclerosis (RRMS). Study 2309 was primarily performed to provide specific safety data for the Gilenya New Drug Application (NDA) that was submitted to the US Food and Drug Administration in December 2009.

The study included 1083 patients across 126 sites in eight countries with most of patients enrolled in the United States, and had a central MRI review and independent EDSS raters. The study included three arms and patients with RRMS were randomized 1:1:1 to fingolimod 1.25 mg, fingolimod 0.5 mg or placebo. Patients who were randomized to the fingolimod 1.25 mg arm were switched to 0.5 mg during the course of the study in a blinded manner based on a determination of superior benefit-risk profile for the 0.5 mg dose in the Phase III studies FREEDOMS and TRANSFORMS.

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.(1) 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 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. 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.(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 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.(1),(2)

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as looking forward to, 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 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. 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.

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

References

(1) 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.

(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; 362:387-401.

(3) Popescu V. et al. Brain atrophy in MS: long-term prognostic value. Poster presented at ECTRIMS, Amsterdam, October 2011.

(4) Havrdová E. et al. Clinical outcomes in subgroups of patients with highly action relapsing-remitting multiple sclerosis treated with Fingolimod (FTY720): Results from the FREEDOMS and TRANSFORMS phase III studies. Poster presented at ECTRIMS, Amsterdam, October 2011.

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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: December 15, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting