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SECURITIES AND EXCHANGE COMMISSION

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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 12, 2012

(Commission File No. 1-15024)

Novartis AG

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MEDIA RELEASE • MEDIA RELEASE • MEDIA RELEASE

New analysis indicates that Novartis drug Gilenya shows significant early effect on reducing brain volume loss at 6 months

- *New analysis of two large Phase III studies demonstrates a significant early treatment effect of Gilenya on relapses and MRI outcomes, including brain volume loss, in MS patients*

- *Data show generally higher adherence rates for once-daily oral Gilenya than injectable DMTs and positive real-world experience*

- *Pooled analysis of core and long-term study data from over 3,500 patients reinforce known safety profile; more than 49,000 patients treated as of August 2012*

Basel, October 12, 2012 New data will be presented at the 28th congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) that reinforce the generally early and sustained efficacy benefit and long-term safety profile for Gilenya® (fingolimod), the first once-daily oral therapy approved to treat relapsing forms of multiple sclerosis (MS)(1),(2).

As the first once-daily oral MS therapy, growing real-world experience reinforces Gilenya s high efficacy and long-term safety profile, said David Epstein, Head of the Pharmaceuticals Division of Novartis Pharma AG. With data showing an early treatment effect on relapses and brain volume loss, Gilenya continues to show positive outcomes for patients and Novartis remains committed to addressing the significant remaining unmet medical need in the MS community.

Analysis shows significant early treatment effect with Gilenya

A new post hoc analysis of two large Phase III studies shows treatment with Gilenya 0.5 mg led to significant benefits on relapse-related outcomes within the first three months and on brain volume loss by six months compared to placebo(1).

There was a significant ($p<0.05$) Gilenya treatment effect on time to first confirmed relapse within three months in both the pivotal FREEDOMS study (n=1272), and FREEDOMS II, the second large Phase III placebo-controlled study (n=1083). The differences between Gilenya and placebo became persistently significant by Day 82 in FREEDOMS and Day 64 in FREEDOMS II, respectively(1).

Furthermore, in the FREEDOMS study, patients-treated with Gilenya 0.5 mg had on average a 35% reduction in brain volume loss compared with placebo at the first MRI evaluation after six months of treatment (mean percent brain volume change of -0.22 for Gilenya *vs.* -0.34 for placebo; p=0.006). In FREEDOMS II, there was a 39% reduction in brain volume loss (mean percent volume change of - 0.23 for Gilenya *vs*. -0.38 for placebo; p=0.012) at six months(1).

Understanding the onset of efficacy is an important consideration in the treatment of MS as early effective treatment may improve patient outcomes, said Professor Ludwig Kappos, MD, Chair of Neurology, University Hospital, Basel, Switzerland. The new

analysis of Phase III data shows a significant early effect of Gilenya on relapses and MRI measures, and further supports its role as a valuable treatment option for relapsing-remitting MS.

New data published on real-world experience and patient adherence

First results from the PANGAEA observational study in Germany indicate that 90% of investigators and 91% of patients rated Gilenya treatment success, defined as efficacy and tolerability, as Good or Very Good (2). PANGAEA is a German registry study aimed to enroll a total of 4,000 patients with a follow-up of five years designed to investigate the efficacy and safety of Gilenya in everyday clinical practice. As of May 2012, one year after initiation of the registry, more than 1,850 patients were enrolled in 475 participating centers. These results also showed an overall safety profile in line with previously reported data(2).

In addition, a separate analysis of time to discontinuation of therapy among MS patients receiving Gilenya and other disease modifying treatments (DMTs) using pharmacy claims in the US (n=1891) show Gilenya-treated patients were significantly less likely to discontinue treatment over the 12 month observation period (Gilenya: 27.8%, other DMT cohorts: 42.7-54.5%; $p<0.01$) and discontinued later than patients using injectable DMTs(3).

Results from more than 3,500 patients further characterize long-term safety profile

A new integrated analysis of safety data from Phase II, Phase III and study extensions for fingolimod (all doses, n=3553) show a safety profile generally consistent with previous results. The total fingolimod exposure was 9,070 patient years, with 1,510 patients treated for more than three years and some for more than seven years(4).

As of August 2012, more than 49,000 patients have been treated with fingolimod in clinical trials and in the post-marketing setting, and there is approximately 52,000 patient years of exposure(5).

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(6). In a recent post hoc sub-group 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(7).

Gilenya is a generally 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 49,000 patients having

been treated in clinical trials and in a post-marketing setting(7). Currently, there is approximately 52,000 patient years of exposure(5).

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(6),(8). 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(6),(8).

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, committed, may, 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 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 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 126,000 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) Chin P.S. et al. Early effect of fingolimod on clinical and MRI related outcomes in relapsing multiple sclerosis. Abstract Presented at ECTRIMS, Lyon, France, October 2012.

(2) Ziemssen T. et al. Study design and first interim results of a registry study to establish long-term safety and pharmaco-economic data on fingolimod (Gilenya®) in multiple sclerosis patients in Germany (PANGAEA). Abstract Presented at ECTRIMS, Lyon, France, October 2012

(3) Neetu A. et al. Comparison of Time to Discontinuation Among Multiple Sclerosis Patients Receiving Fingolimod and Other First-Line Disease Modifying Treatments. Abstract Presented at ECTRIMS, Lyon, France, October 2012.

(4) Cohen J. et al. Long-term safety of fingolimod in relapsing multiple sclerosis: update to integrated analyses of phase 2 and 3 studies and extension phases. Abstract Presented at ECTRIMS, Lyon, France, October 2012.

(5) Novartis data on file.

(6) 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.

(7) 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.

(8) 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.

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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 12, 2012

By: /s/ MALCOLM B. CHEETHAM

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