Novartis data at AAN reinforces commitment to address high unmet medical need and to provide a treatment at every stage of multiple sclerosis

- **New data from three Phase III studies underlines efficacy and adds to growing global experience with Gilenya in more than 50,000 patients worldwide**

- **Data from over 500 patients treated for up to four years reinforces the known, manageable safety profile of once-daily oral Gilenya**

- **Progress reported with Novartis portfolio in studies of patients with primary-progressive MS and secondary-progressive MS, forms of the condition where treatment options are limited**

**Basel, March 13, 2013** – New data will be presented at the 65th annual meeting of the American Academy of Neurology (AAN) that show continued innovation within the Novartis Multiple Sclerosis (MS) portfolio. Growing clinical trial and real-world experience with Gilenya® (fingolimod), the first once-daily oral therapy approved to treat people with relapsing MS (RMS), will be highlighted. Updates on studies of Gilenya in people with primary-progressive MS (PPMS) and the investigational agent BAF312 (siponimod) in people with secondary-progressive MS (SPMS) will also be communicated.

“Novartis is pleased to present new data that underscore Gilenya’s pioneering role in the treatment of MS,” said Dr. Timothy Wright, Global Head Development, Novartis Pharmaceuticals AG. “These results, as well as updates on our investigational MS compound BAF312 (siponimod) show that we are making real progress in our commitment to address unmet medical need in MS and to provide a treatment at every stage of the disease.”

Data from three large Phase III studies will highlight the efficacy of Gilenya in reducing the rate of brain volume loss, the best characterized magnetic resonance imaging (MRI) predictor of long-term disability. There will also be a presentation on the INFORMS study, which is evaluating Gilenya in patients with PPMS. This form of MS affects about 10% of people with MS and follows a steady course of worsening neurologic function for which there are no approved disease modifying treatments.

Additional data will showcase Gilenya’s high efficacy and well characterized and manageable safety profile. Latest information shows that the growing real-world and clinical trial experience base for Gilenya now encompasses more than 50,000 patients and 60,000 patient years of exposure worldwide.

New details will be provided on the design of a Phase III study evaluating the efficacy, safety and tolerability of BAF312 (siponimod) in patients with SPMS, which is a sub-type of MS where there are limited treatment options. The vast majority (85%) of people with relapsing-remitting MS will transition to SPMS; 50% within 10 years of disease onset and 90% within 25 years.
During the AAN congress, Novartis will present a Corporate Therapeutic Update, “The Gilenya Experience: A Focus on the Patient in Clinical Practice,” on Tuesday 19 March at 19:00 – 22:00 PDT at the San Diego Marriott Marquis. Novartis will also host a Patient Advocacy Forum.

Additionally, to support the exchange of educational information within the MS community, the Novartis exhibit at the congress will showcase an expanded Gilenya online and social media platform including the new Gilenya Facebook and GilenyaGo Twitter accounts, YouTube channel, and Gilenya.com mobile site.

**Novartis MS portfolio highlights at AAN include:**

**Gilenya (fingolimod) in relapsing-remitting MS**
- Fingolimod - effect on brain atrophy and clinical/MRI correlations in three Phase III studies – TRANSFORMS, FREEDOMS and FREEDOMS II. Platform presentation, S51.006 Cohen: 21 March, 15:15 hrs. PDT.
- Fingolimod reduces annualized relapse rate in patients with relapsing-remitting multiple sclerosis: FREEDOMS II study subgroup analysis. Poster P07.102, Goodin: 21 March, 14:00 hrs. PDT.
- Long-term safety of fingolimod in patients with relapsing-remitting multiple sclerosis. Results from Phase III FREEDOMS extension study. Poster P01.165, Vollmer: 18 March, 14:00 hrs. PDT.
- Effect of switching from intramuscular interferon b-1a to fingolimod on time to relapse in patients with relapsing-remitting multiple sclerosis enrolled in a 1-year extension of TRANSFORMS. Poster P07.107, Meng: 21 March, 14:00 hrs. PDT.
- Effects of fingolimod on disability progression in patients with disability as measured by EDSS at baseline: post-hoc analyses of FREEDOMS I and II. Poster P04.128, Bergvall: 20 March, 07:30 hrs. PDT.
- Fingolimod observational studies program in patients with relapsing-remitting multiple sclerosis: Study designs. Poster P07.100, Butzkueven: 21 March, 14:00 hrs. PDT.

**Gilenya (fingolimod) in primary progressive MS**
- Study design and baseline characteristics of the INFORMS study: Fingolimod in patients with primary progressive multiple sclerosis. Poster P07.116, Miller: 21 March, 14:00 hrs. PDT.

**BAF312 (siponimod) in secondary-progressive MS**
- Siponimod (BAF312) for the treatment of secondary-progressive multiple sclerosis: design of the Phase III EXPAND trial. Poster P07.126, Kappos: 21 March, 14:00 hrs. PDT.

In addition to marketed products Gilenya and Extavia® (interferon beta-1b for subcutaneous injection) the Novartis MS portfolio includes investigational compounds BAF312 (siponimod), and AIN457 (secukinumab), a fully human monoclonal antibody inhibiting interleukin-17A (IL-17A), a key pro-inflammatory cytokine.

**About Gilenya**
Gilenya is the first oral therapy approved to treat relapsing forms of MS and the first in a new class of compounds called sphingosine 1-phosphate receptor modulators\(^\text{15,16}\). Gilenya is thought to act on inflammatory processes implicated in the MS disease process\(^\text{15,16}\).

Data has shown significant efficacy with Gilenya in reducing relapses and significant slowing of six-month disability progression sustained at four years\(^\text{17}\). Nearly half of Gilenya patients were disease-free after one year of treatment\(^\text{18}\) and in the pivotal FREEDOMS study eight out of ten patients remained on treatment at two years\(^\text{10}\).
Gilenya is the only oral treatment shown to consistently decrease brain volume loss, the best characterized magnetic resonance imaging (MRI) predictor of long-term disability.

Gilenya 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) at one year in a pivotal head-to-head trial in patients with relapsing-remitting multiple sclerosis11. In a 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 treatment19.

In clinical trials, Gilenya was generally well-tolerated with a manageable safety profile. 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 bronchoconstriction10,11. 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 groups10,11.

Gilenya is licensed from Mitsubishi Tanabe Pharma Corporation.

About BAF312 (siponimod)

BAF312 (siponimod) is an investigational compound in the Novartis Multiple Sclerosis (MS) portfolio. BAF312 is an oral, selective modulator of the sphingosine 1-phosphate (S1P) receptor subtypes 1 and 5 (S1P1, 5R modulator) with a short half-life leading to relatively rapid washout (6 days)20. The short half-life allows for a rapid recovery of blood lymphocyte counts following treatment discontinuation21. In the Phase II BOLD study, BAF312 demonstrated a favorable safety and tolerability profile when an initial dose titration regimen was used at the start of treatment. The most common adverse events were headache, bradycardia, dizziness and nasopharyngitis21.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "commitment," "will," or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Gilenya, potential future marketing submissions or approvals for other MS products, or regarding potential future revenues from Gilenya or such other products. 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 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 any other MS products will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that Gilenya or any other such products 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; competition in general, including potential competition from additional newly-approved oral multiple sclerosis treatments; unexpected regulatory actions or delays or government regulation generally; 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 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 128,000 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:


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