New data at AAN to confirm efficacy of Novartis’ Gilenya® across four key measures of MS disease activity, including brain volume loss

- Gilenya reduced relapse rates, new MRI lesion counts, brain volume loss and disability progression in previously-treated MS patients with high disease activity
- Data at AAN showed significantly more Gilenya-treated patients (vs. patients on placebo) had brain volume loss rates comparable to people without MS
- Generation of scientifically meaningful data, highlighted by 38 abstracts at AAN, is central to Novartis’ commitment to address the unmet needs of MS community

Basel, April 23, 2014 – New analyses of pooled data from the FREEDOMS and FREEDOMS II trials will be presented at the 66th American Academy of Neurology (AAN) Annual Meeting in Philadelphia, Pennsylvania, and will show the consistent efficacy of Gilenya® (fingolimod) on four key measures of multiple sclerosis (MS) disease activity – reducing relapses, new MRI lesion counts, brain volume loss and disability progression. Demonstrating benefit on these four measures is important in order to improve the course of MS and ultimately address the loss of function (e.g. problems walking or difficulty with mental tasks) experienced by patients with MS. An additional analysis of FREEDOMS and FREEDOMS II will show that significantly more Gilenya-treated patients (vs. patients on placebo) had brain volume loss rates comparable to people without MS.

Given that brain volume loss, measured by Magnetic Resonance Imaging (MRI), starts early in the disease course and is correlated with long-term disability (both physical and cognitive), a treatment benefit on this measure will be important for patients with MS.

“These new analyses provide further evidence of how Gilenya impacts four key measures of MS disease activity,” said David Epstein, Division Head, Novartis Pharmaceuticals. “Additionally, new data reinforcing Gilenya’s positive effect on brain volume loss are of significant interest to the MS community. People with MS lose brain volume up to three to five times faster than people without MS and these data will highlight the importance of a treatment that can minimize brain volume loss in patients.”

Novartis is also presenting trial design information on PARADIGMS, the first controlled clinical trial investigating a disease-modifying therapy (DMT) in pediatric MS patients. In collaboration with regulatory agencies and international leaders in pediatric MS, Novartis has developed the PARADIGMS study to evaluate the efficacy and safety of fingolimod versus an injectable interferon beta 1-a treatment in pediatric patients treated for 24 months. Pediatric MS is uncommon, given that only 3-5% of all MS cases start in this age range. There are currently no approved treatments for pediatric MS, and no controlled studies of MS therapies have been conducted in this population.

Novartis MS portfolio highlights at AAN include:
Gilenya® (fingolimod) in relapsing-remitting MS

- Proportion of patients with brain volume loss comparable to healthy adults in fingolimod phase 3 multiple sclerosis studies – Platform presentation S13.006, De Stefano: April 29, 14:15 EST
- Efficacy of fingolimod in pre-treated patients with disease activity: pooled analyses of FREEDOMS and FREEDOMS II – Poster P3.174, Bergvall: April 29, 15:00 EST
- Consistent reduction in the annualized rate of brain volume loss across phase 3 core and extension trials of fingolimod in relapsing multiple sclerosis – Poster P3.180, Radue: April 29, 15:00 EST
- Efficacy benefits of fingolimod 0.5 mg once daily in patients previously treated with glatiramer acetate: pooled analysis of the phase 3, placebo-controlled FREEDOMS and FREEDOMS II studies in relapsing multiple sclerosis – Poster P3.193, Jeffrey: April 29, 15:00 EST
- Four-year Expanded Disability Status Scale (EDSS) outcomes in patients treated with fingolimod in the phase 3 and extension trial program – Poster P3.185, Cree: April 29, 15:00 EST
- Long-term safety of fingolimod: interim evaluation of data from the LONGTERMS trial – Poster P2.210, Cohen: April 29, 07:30 EST
- Relapse rates among patients with multiple sclerosis who switch from interferon therapy to fingolimod or glatiramer acetate: a retrospective US claims database analysis – Poster P7.211, Lahoz: May 1, 15:00 EST

Fingolimod in pediatric MS

- Fingolimod in pediatric MS: design of a double-blind study versus interferon beta-1a IM (PARADIGMS) – Poster P2.238, Chitnis: April 29, 07:30 EST

BAF312 (siponimod) in relapsing-remitting MS

- Safety and efficacy of siponimod (BAF312) in patients with relapsing-remitting multiple sclerosis: Results from dose-blinded extension phase of BOLD study – Poster P3.151, Kappos: April 29, 15:00 EST

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic disorder of the central nervous system (CNS) that disrupts the normal functioning of the brain, optic nerve and spinal cord15. The evolution of MS results in an increasing loss of both physical (e.g. difficulty with walking) and cognitive (e.g. problems with mental tasks or memory) function16. This has a substantial negative impact on the approximately 2.3 million people worldwide affected by MS17, a disease that begins in early adulthood, most often between the ages of 20 and 4018.

The loss of physical and cognitive function is driven by two main types of damage that both contribute to widespread loss of neurons (nerve cells in the brain and spinal cord that transmit impulses): discrete inflammatory lesions, focal damage, in the brain that can clinically manifest as relapses; and ongoing, more diffuse damage that starts early in the disease and causes the progressive loss of brain tissue, including neurons, and over time is associated with both physical and cognitive problems19-21.

About Gilenya

Gilenya is the only oral disease modifying therapy (DMT) that works on four key measures of multiple sclerosis (MS) disease activity – relapses, MRI lesions, brain volume loss and disability progression22-26.

Gilenya reduces both the distinct inflammatory lesions in the brain (focal damage) that can clinically manifest as relapses, and the ongoing, underlying damage in the brain (diffuse damage) that starts early in the disease19-21,27-28. Diffuse damage often goes unnoticed, causes the loss of neurons and over time is associated with both physical and cognitive problems19-21. Gilenya’s reduction of both focal damage and diffuse damage is
due to its impact on the inflammatory process (peripheral action) and its ability to enter the CNS and impact from within the CNS (central action)\textsuperscript{27-29}. It is by addressing both focal and diffuse damage that the course of MS can be effectively impacted, helping to preserve a patient’s physical (e.g. difficulty with walking) and cognitive (e.g. problems with mental tasks or memory) function.

To date, more than 91,500 patients worldwide have been treated with Gilenya in both clinical trial and post-marketing settings\textsuperscript{29}.

**About Novartis in Multiple Sclerosis**

Novartis is committed to the research and development of new treatment options to offer the right treatment to the right patient at the right time, to meet patients’ needs at every stage of disease with innovative and targeted drugs.

In addition to its ongoing development program for Gilenya in primary progressive MS (PPMS), pediatric MS and chronic inflammatory demyelinating polyneuropathy (CIDP), the Novartis MS portfolio includes Extavia\textsuperscript{8} (interferon beta-1b for subcutaneous injection). Investigational compounds include BAF312 (siponimod), currently in Phase III clinical development and being developed as the first oral therapy for secondary progressive MS (SPMS), and VAY736, an anti-B-cell compound for MS that is currently being investigated in proof of concept studies. Novartis is also exploring the IL-17 pathway in MS.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as “to confirm,” “will,” “commitment,” “can,” “is also presenting,” “committed,” “ongoing,” “investigational,” “being developed,” “being investigated,” “exploring,” or similar terms, or by express or implied discussions regarding potential future indications or labeling for Gilenya, potential future marketing submissions or approvals for the other investigational compounds in the Novartis MS portfolio, or regarding potential future revenues from any or all of the products and investigational compounds in the Novartis MS portfolio, including Gilenya. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking 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 of the investigational compounds in the Novartis MS portfolio will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that any of the products and investigational compounds in the Novartis MS portfolio will be commercially successful in the future. In particular, management’s expectations regarding these products could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company’s ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission.

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 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 136,000 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
25. Kappos L et al. Phase 3 FREEDOMS study extension: fingolimod (FTY720) efficacy in patients with relapsing-remitting multiple sclerosis receiving continuous or placebo-fingolimod switched therapy for up to 4 years. Poster presented at: 28th Congress of the European Committee for Treatment and Research in Multiple Sclerosis; October 10-13, 2012; Lyon, France. Poster P979.

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