Real-world evidence showed superiority of Novartis’ Gilenya® to reduce MS relapse rates compared to interferons or glatiramer acetate

- **Real-world data showed Gilenya reduced the annualized relapse rate and risk of relapse by around 50% versus interferons or glatiramer acetate**

- **Reducing the frequency and probability of future relapses in patients with MS is a key treatment goal, as relapses can significantly advance an individual’s level of disability**

- **Recovering from a relapse can take weeks or months for a patient with MS, and approximately half of all relapses may leave lasting effects**

**Basel, October 3, 2013** – Novartis announced today findings from an international multiple sclerosis (MS) registry and a US health claims data base which showed the real-world superiority of Gilenya® (fingolimod) in reducing risks of relapses compared to standard therapies1-3. These data confirm the positive results seen in clinical trials with Gilenya, and were presented at the ongoing 29th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Copenhagen, Denmark.

Relapses can make life unpredictable for patients with MS and they can potentially significantly advance an individual's level of disability4. MS patients’ clinical outcomes are regularly assessed and switching between disease-modifying therapies (DMTs), to reduce the rate or likelihood of a relapse, is a frequent treatment strategy.

“Controlling relapses and preventing disability are key treatment goals for patients with MS,” said David Epstein, Division Head of Novartis Pharmaceuticals. “It is encouraging to see that the benefits of Gilenya, which is the only disease modifying treatment proven in clinical studies to have a superior relapse reduction compared to an active comparator, are now confirmed in the real-world setting.”

The ‘MSBase study’, a global, longitudinal, observational registry for MS involving 60 centers in 26 countries and US administrative claims data from the ‘IMS PharMetrics PlusTM Database’ were interrogated for information on the impact on MS relapses of switching to either oral Gilenya or to one of the standard injectable therapies – an interferon or glatiramer acetate. Collectively, analysis of patient data from these large, real-world databases (416 patients from MSBase and 933 patients from the IMS PharMetrics PlusTM Database) showed that treatment with Gilenya reduced the annualized relapse rate and risk of relapse by approximately 50% compared to therapy with an interferon or glatiramer acetate treatment1-3. They also showed that even amongst patients with MS who have a history of relapse, switching to Gilenya was associated with significant and clinically meaningful reductions in the number of relapses and the probability of experiencing a relapse compared to switching to an interferon or glatiramer acetate1-3.
Following first approvals in 2010, once daily oral Gilenya is now available in more than 75 countries and more than 71,000 patients have been treated in both the clinical trial and post-marketing settings with over 87,000 patient years of exposure.

About Multiple Sclerosis
While its exact cause is unknown, multiple sclerosis (MS) is an autoimmune disease of the central nervous system (CNS) that causes the body to turn against itself by mistaking normal cells for foreign cells. In MS the myelin sheath, the covering that protects nerve fibers, is damaged by the inflammation that occurs when the body’s immune cells attack the nervous system. This neuro-inflammatory damage can occur in any area of the brain, optic nerve and spinal cord and cause a range of physical and mental problems including loss of muscle control and strength, vision, balance, sensation and mental function. Up to 2.5 million people worldwide are affected by MS, most often younger people between the ages of 20 and 40.

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. It is thought that Gilenya works in two ways against the destructive processes that drive MS disease progression by affecting not only the immune system to reduce inflammatory damage but also the CNS to promote neuroprotection and repair. Gilenya is thought to act by preventing lymphocytes (the cells that cause inflammation and damage in the CNS) from leaving the lymphoid tissues, thus reducing their entry into the central nervous system and potential for damage. Gilenya is also able to cross the blood-brain barrier and act on the neurodegeneration process in the brain and spinal cord.

Gilenya is the only oral MS treatment that provides early and long-term reduction in the rate of brain volume loss and high efficacy across all 4 disease activity measures (disability progression, relapses, MRI activity, brain volume loss). In clinical trials, Gilenya exhibited a well-characterized safety profile and very good tolerability profile. The most common side effects were headache, hepatic enzymes increased, influenza, sinusitis, diarrhea, back pain, and cough. To date, more than 71,000 patients have been treated with Gilenya demonstrating a positive benefit-risk profile in clinical study and real-world settings.

Gilenya is licensed from Mitsubishi Tanabe Pharma Corporation.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by terminology such as “goal,” “can,” “may,” “potentially,” “goals,” 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 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; 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 131,000 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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