Data at ECTRIMS to confirm Novartis’ Gilenya® long-term efficacy on reducing brain volume loss and real-world relapse rates in MS

- New four-year data will show continued Gilenya treatment reduced brain volume loss in MS patients compared to delaying treatment with Gilenya by two years
- Data will strengthen the link between brain volume loss and disability progression, highlighting the importance of reducing brain volume loss in patients with MS
- Real-world patient data will confirm superiority of Gilenya compared to standard therapies (interferon and glatiramer acetate) in reducing MS relapse rates

Basel, September 25, 2013 – New data showing the benefits of Gilenya® (fingolimod) on patient outcomes in multiple sclerosis (MS) will be presented at the 29th Congress of the European Committee for Research and Treatment in Multiple Sclerosis (ECTRIMS) in Copenhagen, Denmark, adding to the growing evidence base for Gilenya in both clinical trial and real-world settings.

New four-year data from the pivotal FREEDOMS and FREEDOMS extension studies plus a separate analysis of three studies (FREEDOMS, FREEDOMS II and TRANSFORMS) will show the benefits of continued Gilenya treatment on brain volume loss compared to delayed treatment of two years. These data will reinforce what we know about the correlation between brain volume loss and disability, underlining the need for effectively addressing brain volume loss in patients with MS. Data from international and U.S. real-world databases will also confirm the favorable effect of Gilenya on reducing relapse rates for patients with MS.

“It’s very encouraging for patients that we continue to confirm the long term benefits Gilenya delivers in MS,” said Dr. Timothy Wright, Global Head Development, Novartis Pharmaceuticals. “These new data will emphasize the importance of reducing brain volume loss and relapse rates for patients, with increasing evidence on the effectiveness of Gilenya from both clinical and real-world settings.”

Novartis MS portfolio highlights at ECTRIMS include:
- Six poster presentations on the importance of, and impact of Gilenya on, brain volume loss.
- Ten poster presentations on the efficacy of Gilenya both in clinical trials and real-world settings.
- Nine posters, three oral presentations will reinforce the tolerability and safety profile of Gilenya.
- Eight poster presentations discuss the real-world evidence for Gilenya.
- Nine poster presentations will reinforce success of Gilenya in a real-world setting.
- Eleven posters highlight the breadth of Novartis’ pipeline.

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).
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 enduring high efficacy across all key disease activity measures. 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 “to confirm,” “will,” “encouraging,” “continue,” “pipeline,” “investigational,” or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Gilenya, potential future marketing approvals for investigational MS therapies, or regarding potential future revenues from Gilenya or from such investigational therapies. 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 other Novartis investigational MS therapies will be submitted or approved for sale in any country, or at any particular time. Neither can there be any guarantee that such products will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding these products 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 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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References

Novartis Media Relations

Central media line : +41 61 324 2200
Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Katrina Lucking
Novartis Global Pharma Communications
+41 61 324 12 18 (direct)
+41 79 171 8267 (mobile)
katrina.lucking@novartis.com

e-mail: media.relations@novartis.com
Novartis Investor Relations

**Central phone:** +41 61 324 7944
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

**North America:**
Stephen Rubino +1 862 778 8301
Jill Pozarek +1 212 830 2445

E-mail: investor.relations@novartis.com