FDA approves supplemental new drug application for Novartis therapy Gilenya™ to include data showing reduction in T1 lesions in MS, a marker of disease activity

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- - Gilenya-treated patients had fewer T1 gadolinium (Gd)- enhancing lesions versus those treated with interferon beta-1a IM at 12 months and placebo at 24 months
- - More than 11,000 people in U.S. have been prescribed Gilenya since FDA approval in September 2010; now approved in more than 40 countries

East Hanover, NJ, August 1, 2011 – Novartis Pharmaceuticals Corporation announced today the U.S. Food and Drug Administration's approval of a supplemental New Drug Application (sNDA) for Gilenya™ (fingolimod) that includes T1 Gd-enhancing magnetic resonance imaging (MRI) data. Gilenya is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS) in adults. It can decrease the number of MS flare-ups (relapses). It does not cure MS but can help slow down the physical problems that MS causes.

T1 Gd-enhancing lesions are areas of active inflammation in the central nervous system (CNS) and represent an important marker of disease activity in people with MS. "Neurologists commonly use gadolinium contrast MRI activity to assess for active inflammation in people living with MS," said Barry Singer, MD, Director of The MS Center for Innovations in Care at Missouri Baptist Medical Center. "These data show that treatment with Gilenya helped to significantly reduce contrast MRI activity in people with relapsing-remitting MS."

As a result of the approved sNDA, the Clinical Studies section 14 of the Gilenya Prescribing Information has been updated to include T1 MRI findings from the 12 month TRANSFORMS and 24 month FREEDOMS studies. These phase III pivotal trials were submitted to the FDA to support the approval of Gilenya.

At 12 months, the mean number of Gd-enhancing T1 lesions was significantly lower for patients treated with Gilenya (0.5 mg) compared to patients taking interferon beta-1a IM, 0.2 vs. 0.5 respectively ($p<0.001$). Gilenya (0.5 mg) demonstrated a similar effect at 24 months 0.2 vs. 1.1, when compared to placebo ($p<0.001$).

The Gilenya Prescribing Information Section 5.5 was also updated in May 2011 to reflect the period of time in which liver transaminase elevations occurred, noting the majority of elevations occurred within 6-9 months after starting Gilenya treatment (original Prescribing Information indicated within 3-4 months).

About Gilenya
More than 11,000 people in the U.S. have been prescribed Gilenya since it became commercially available on October 4, 2010. Novartis continues to regularly submit Gilenya safety updates to the FDA and health authorities worldwide. The safety profile of Gilenya remains consistent with the current U.S. prescribing information.

In a two-year study, Gilenya reduced MS relapses by 54% ($P<0.001$; primary endpoint) and showed a 30% reduction in the risk of 3-month confirmed disability ($P<0.05$; key secondary endpoint) compared to placebo.

Data from a one-year study showed Gilenya (0.5 mg) reduced relapses by 52% (P<0.001; primary endpoint), while there was no significant difference in 3-month confirmed disability (P=0.21) compared with interferon beta-1a IM (Avonex®), one of the most commonly prescribed treatments for MS. Gilenya also reduced disease activity as measured by the number of new and newly enlarged T2 lesions on MRI scans compared to interferon beta-1a IM (1.6 vs 2.6, respectively, P=0.002; key secondary endpoint) at one year and at two years compared to placebo (2.5 vs 9.8, respectively, P<0.001).

Licensed from Mitsubishi Tanabe Pharma Corporation, Gilenya is the first oral treatment in a new class of drugs called sphingosine 1-phosphate receptor (S1PR) modulators. Approved in more than 40 countries including the U.S., Canada and the countries of the European Union, Gilenya has been studied in phase III clinical trials of over 2500 patients with relapsing-remitting MS. In MS, the immune system damages the myelin sheath that protects nerve fibers in the central nervous system (CNS). As shown in animal models, Gilenya lowers the number of white blood cells (lymphocytes) in a patient's blood. How Gilenya works is unknown, but it is thought that Gilenya keeps more lymphocytes inside the lymph nodes, so that fewer can be released to attack the nerve fibers in the brain, spinal cord, and the eyes. These lymphocytes in the lymph nodes and in the blood continue to function with Gilenya treatment. Gilenya only keeps lymphocytes inside the lymph nodes from leaving. It doesn't destroy them. If Gilenya treatment is stopped for any reason, the number of lymphocytes circulating in the body increases over the first few days and gradually returns to normal within 1 to 2 months.

Important Safety Information
Gilenya may cause serious side effects such as:

Slow heart rate, especially about 6 hours after a patient's first dose. If a patient's heart rate slows down, they might feel dizzy or tired, or be aware of a slow or irregular heartbeat. A doctor will watch patients for the first 6 hours after their first dose for any serious side effects. If a patient experiences slow heart rate, it will usually return to normal within 1 month. Patients should call their doctor if at any time they have dizziness, tiredness, or a slow or irregular heartbeat. If a patient stops taking Gilenya for 2 weeks or more, they will need to repeat this observation.

Increased risk of serious infections. Gilenya lowers the number of white blood cells (lymphocytes) in a patient's blood. This will usually go back to normal within 2 months of stopping Gilenya. Doctors may do a blood test before a patient starts Gilenya. Increased risk of infection was seen with doses higher than the approved dose (0.5 mg). Two patients died who took higher-dose Gilenya (1.25 mg) combined with high-dose steroids. Patients should call their doctor right away if they have fever, tiredness, body aches, chills, nausea, or vomiting.

Macular edema, a vision problem, can cause some of the same vision symptoms as an MS attack (optic neuritis), or no symptoms. Macular edema usually starts in the first 3 to 4 months after starting Gilenya. Doctors should test a patient's vision before they start Gilenya; 3 to 4 months after they start Gilenya; and any time they notice vision changes. Vision problems may continue after macular edema has gone away. A patient's risk of macular edema may be higher if they have diabetes or have had an inflammation of their eye (uveitis). Patients should call their doctor right away if they have blurriness, shadows, or a blind spot in the center of their vision; sensitivity to light; or unusually colored vision.

Breathing problems. Some patients have shortness of breath. Patients should call their doctor right away if they have trouble breathing.

Liver problems. A doctor should do blood tests to check a patient's liver before they start Gilenya. Patients should call their doctor right away if they have nausea, vomiting, stomach pain, loss of appetite, tiredness,

dark urine, or if their skin or the whites of their eyes turn yellow.

Increases in blood pressure (BP). BP should be monitored during treatment.

Gilenya may harm an unborn baby. Patients should talk to their doctor if they are pregnant or planning to become pregnant. Women who can become pregnant should use effective birth control while on Gilenya, and for at least 2 months after stopping. If a patient becomes pregnant while taking Gilenya, or within 2 months after stopping, they should tell their doctor right away. Women who take Gilenya should not breast-feed, as it is not known if Gilenya passes into breast milk. A pregnancy registry is available for women who become pregnant during Gilenya treatment. Call 1-877-598-7237 for more information.

Patients should tell their doctor about all their medical conditions, including if they had or now have an irregular or abnormal heartbeat; a heart rate less than 55 beats a minute; heart problems; a history of fainting; a fever or infection, or if they are unable to fight infections; eye problems; diabetes; breathing or liver problems; or high blood pressure. Patients should also tell their doctor if they have chicken pox or have received the vaccine for chicken pox. A doctor may do a test for the chicken pox virus, and patients may need to get the vaccine for chicken pox and wait 1 month before starting Gilenya.

Patients should tell their doctor about all the medicines they take, including medicines for heart problems or high blood pressure; medicines that could increase their chance of infections, such as medicines to treat cancer or control their immune system; or ketoconazole (an antifungal) by mouth. If taken with Gilenya, serious side effects may occur. Patients should not get certain vaccines while taking Gilenya, and for at least 2 months after stopping.

The most common side effects with Gilenya were headache, flu, diarrhea, back pain, abnormal liver tests, and cough.

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying Important Product Information, including Medication Guide.

About Multiple Sclerosis
While there is still much to be understood about multiple sclerosis, it is thought to be an autoimmune disease of the central nervous system that is chronic, progressive and often disabling. It affects over 400,000 Americans and more than 2.1 million people worldwide. The most common forms of the disease, relapsing forms of MS, are characterized by exacerbations or flare-ups interspersed with periods of disease remission. Typically, MS strikes in early adulthood.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by terminology such as “can,” or similar expressions, or by express or implied discussions regarding potential submissions or approvals for 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. 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 regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical

data and unexpected additional analysis of existing clinical data; competition in general; government, industry and general public pricing pressures; 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 Pharmaceuticals Corporation researches, develops, manufactures and markets innovative prescription drugs used to treat a number of diseases and conditions, including cardiovascular, dermatological, central nervous system, bone disease, cancer, organ transplantation, psychiatry, infectious disease and respiratory. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only company with leading positions in these areas. In 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 121,000 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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Novartis Media Relations

Julie Masow
Novartis Corporation
+1 212 830 2465 (direct)
+1 862 579 8456 (mobile)
julie.masow@novartis.com

e-mail: us.mediarelations@novartis.com

Maureen Byrne
Novartis Communications
+1 862 778 1518 (direct)
+1 862 714 0063 (mobile)
maureen.byrne@novartis.com

Full Prescribing Information

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