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Novartis announces update to United States prescribing information for MS therapy Gilenya following FDA review

- *Prescribing information (PI) includes new patient selection parameters based on certain cardiovascular considerations to aid in identifying patients for Gilenya*
- *Updated Gilenya prescribing information provides further guidance to healthcare providers regarding treatment initiation*
- *The updated PI does not affect the management of patients currently on Gilenya, unless they discontinue treatment and need to reinitiate*

East Hanover, NJ April 20, 2012 – Novartis today announced updates to the United States prescribing information for Gilenya™ (fingolimod), a once-daily oral therapy proven to reduce the number of relapses and slow disability progression in patients with relapsing forms of multiple sclerosis (MS). The changes follow a review by the U.S. Food and Drug Administration (FDA) announced in December 2011 and confirm that Gilenya is an important treatment option for appropriate patients.

Novartis has agreed with the FDA to update the U.S. prescribing information for Gilenya to include updated patient selection parameters based on certain cardiovascular considerations to aid in the identification of patients for Gilenya. The updated prescribing information also includes specific recommendations for treatment initiation for patients with relapsing forms of MS.

The updated prescribing information for Gilenya recommends that all patients initiating treatment should have an electrocardiogram (ECG) prior to dosing and at the end of the six-hour observation period along with hourly measurement of blood pressure and heart rate. The updated prescribing information does not affect the management of patients currently on Gilenya, unless they discontinue treatment and need to reinitiate. There are revised recommendations on how to reinitiate therapy should Gilenya be discontinued. Patients should not make any changes to any medications they are taking, including Gilenya, without consulting their doctor.

In addition, the updated prescribing information recommends that patients with certain pre-existing cardiac conditions or those taking concomitant heart rate lowering medications be evaluated by a physician prior to the first dose. If treated with Gilenya, these patients should be monitored overnight with continuous ECG in a medical facility after the first dose. Experience with the use of Gilenya in such patients is limited.

The updated prescribing information includes new contraindications. Gilenya is contraindicated in patients with history or presence of certain cardiac conditions, including heart attack or stroke in the past six months, second- and third-degree atrioventricular (AV) block and other serious cardiac rhythm disturbances, and in patients treated with certain anti-arrhythmic drugs.

As of February 2012, approximately 36,000 patients have been treated with Gilenya in clinical trials and in the post-marketing setting worldwide.

“Gilenya represents an important treatment option for relapsing forms of MS,” said Barry Singer, MD, Director, MS Center for Innovations in Care, Missouri Baptist Medical Center. “Choosing appropriate patients for Gilenya therapy and patient safety is essential.”

Novartis will be communicating these updates to the U.S. prescribing information to physicians and patients through established field force and patient communication channels. To help the MS community understand these new recommendations, Novartis will be posting information for patients at www.Gilenya.com. Healthcare providers and patients may also contact Novartis directly at 1-888-NOW-NOVA.

The Company is committed to helping healthcare providers implement the updated prescribing information recommendations. Novartis continues to offer first-dose observation capabilities via the Gilenya Assessment Network (GAN). The GAN is a network of clinical centers that provide assessments and screenings that may be needed by patients taking Gilenya. It currently comprises more than 200 sites around the country and is growing rapidly.

Also today, the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) confirmed a positive benefit-risk profile of Gilenya. The CHMP recommended updates to the product information in the European Union that provide further guidance to healthcare providers regarding treatment initiation with Gilenya in MS patients. Those recommendations apply only to use of Gilenya in European Union countries.

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 between the ages of 20 and 50 and affects women twice as frequently as men.

About Gilenya™ (fingolimod)
Gilenya, licensed from Mitsubishi Tanabe Pharma Corporation, is the first in a new class of drugs called sphingosine 1-phosphate receptor (S1PR) modulators. Gilenya works by targeting S1P receptors that exist in the cardiovascular, central nervous and immune systems. In targeting the S1P receptor, initiation of treatment with Gilenya is known to be associated with bradycardia (slowing of the heart rate) and atrioventricular (AV) block (a problem with electrical impulse conduction in the heart).

Gilenya is an effective prescription medicine proven to decrease the number of MS flare-ups (relapses) and slow down the physical problems MS causes. In a two-year study, Gilenya reduced annualized MS relapses by 54% (0.18 vs 0.40; $P<0.001$) and 52% (0.16 vs 0.33; $P<0.001$) at one year, when compared with placebo and interferon beta-1a IM, respectively. Additionally, Gilenya showed a 30% reduction in the risk of 3-month confirmed disability ($p<0.05$; key secondary endpoint) compared to placebo.

Indication

Gilenya is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS) in adults. Gilenya can decrease the number of MS flare-ups (relapses). Gilenya does not cure MS, but it can help slow down the physical problems that MS causes.

Important Safety Information

You should not take Gilenya if in the last 6 months you experienced heart attack, unstable angina, stroke or warning stroke, or certain types of heart failure. Do not take Gilenya if you have an irregular or abnormal heartbeat (arrhythmia) or if you take medicines that change your heart rhythm.

Gilenya may cause serious side effects such as:

- Slow heart rate, especially after your first dose. A test to check the electrical activity of your heart (ECG) will be performed before and six hours after your first dose. Your pulse and blood pressure should be checked every hour while you stay in a medical facility during this time. If your heart rate slows down too much, you might feel dizzy or tired, or feel like your heart is beating slowly or skipping beats. Symptoms can happen up to 24 hours after your first dose. After 6 hours, if your ECG shows any heart problems or if your heart rate is still too low or continues to decrease, you will continue to be watched by a health care professional. If you have any serious side effects after your first dose, especially those that require treatment with other drugs, you will stay in a medical facility to be watched overnight and for at least 6 hours after your second dose of Gilenya the next day. If you experience slow heart rate, it will usually return to normal within 1 month. Call your doctor or go to the nearest emergency room right away if you have any symptoms of a slow heart rate. If you stop taking Gilenya for more than 14 days, you will need to repeat this observation.

- Increased risk of serious infections. Gilenya lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 2 months of stopping Gilenya. Your doctor may do a blood test before you start 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. Call your doctor right away if you have fever, tiredness, body aches, chills, nausea, or vomiting.

- Macular edema, a vision problem that 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. Your doctor should test your vision before you start Gilenya; 3 to 4 months after you start Gilenya; and any time you notice vision changes. Vision problems may continue after macular edema has gone away. Your risk of macular edema may be higher if you have diabetes or have had an inflammation of your eye (uveitis). Call your doctor right away if you have blurriness, shadows, or a blind spot in the center of your vision; sensitivity to light; or unusually colored vision.

- Breathing problems. Some patients have shortness of breath. Call your doctor right away if you have trouble breathing.

- Liver problems. Your doctor should do blood tests to check your liver before you start Gilenya. Call your doctor right away if you have nausea, vomiting, stomach pain, loss of appetite, tiredness, dark urine, or if your skin or the whites of your eyes turn yellow.

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

Gilenya may harm your unborn baby. Talk to your doctor if you 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 you become

pregnant while taking Gilenya, or within 2 months after stopping, tell your 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.

Tell your doctor about all your medical conditions, including if you had or now have an irregular or abnormal heartbeat; heart problems; a history of fainting; a fever or infection, or if you are unable to fight infections; eye problems; diabetes; breathing or liver problems; or high blood pressure. Also tell your doctor if you have had chicken pox or have received the vaccine for chicken pox. Your doctor may do a test for the chicken pox virus, and you may need to get the vaccine for chicken pox and wait 1 month before starting Gilenya.

Tell your doctor about all the medicines you take, including medicines for heart problems or high blood pressure or other medicines that may lower your heart rate or change your heart rhythm; medicines that could increase your chance of infections, such as medicines to treat cancer or control your immune system; or ketoconazole (an antifungal) by mouth. If taken with Gilenya, serious side effects may occur. You 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.

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

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “believe,” “will,” “committed,” “recommended,” “recommendations,” or similar expressions, or by express or implied discussions 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 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, including the finalization of EU review of the Gilenya label; 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; 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 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, NJ, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which 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 2011, the Group's continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 124,000 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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