Two new analyses reinforce consistent efficacy of Novartis therapy Gilenya across wide range of relapsing MS patients

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- • Data from FREEDOMS study show Gilenya reduced relapses in patients who discontinued another MS therapy due to side effects or inadequate efficacy
- • Analyses of five clinical studies show Gilenya, reduced relapse rates nearly 50% and increased proportion of patients free from relapse
- • More than 36,000 patients worldwide have been treated with Gilenya, the first once-daily oral drug approved to treat relapsing forms of MS

East Hanover, NJ, May 31, 2012 – A new post-hoc analysis of data from the FREEDOMS study demonstrated that the efficacy of Gilenya™ (fingolimod) in patients with relapsing-remitting multiple sclerosis (MS) who had previously been treated with another MS therapy, was generally consistent with the efficacy seen among the total population included in the clinical trial. An additional analysis looked at the efficacy of Gilenya compared to interferon beta 1a IM or placebo across three Phase III and two Phase II studies, representing more than 4,000 patients in multiple geographies. These data are being presented at the Consortium of Multiple Sclerosis Centers (CMSC) annual meeting, May 30-June 2 in San Diego.

The pivotal, two-year, phase III FREEDOMS study included 1,272 patients with relapsing-remitting MS and examined the safety and efficacy of Gilenya (1.25 mg and 0.5 mg) compared to placebo. Gilenya 0.5 mg demonstrated a statistically significant 54% reduction in annualized relapse rate (ARR) compared to placebo at two years. The new post-hoc analysis assessed the efficacy of Gilenya compared to placebo among patients who had received previous treatment with disease modifying therapies (DMTs) and showed that Gilenya 0.5 mg reduced the ARR compared to placebo in all cases.

Among the patients who discontinued their prior treatment due to inadequate efficacy, Gilenya 0.5 mg reduced the ARR by 69% compared to placebo (Gilenya 0.5 mg, n=41, ARR=0.291; placebo, n=38, ARR=0.931). For patients who stopped their prior treatment due to side effects, Gilenya 0.5 mg reduced the ARR by 36% compared to placebo (Gilenya 0.5 mg, n=73, ARR=0.329; placebo, n=79, ARR=0.517). Patients also demonstrated reductions in relapses compared to placebo regardless of duration of prior DMT treatment. Gilenya 0.5 mg also reduced annualized relapse rate compared to placebo for patients who had never previously received DMTs for their MS [placebo 0.456, Gilenya 0.166, P<0.0001.]

“Treatment side effects or suboptimal response often leads to switching disease modifying therapy (DMT) for patients with relapsing forms of multiple sclerosis,” said Barry Singer, MD, Director of The MS Center for Innovations in Care at Missouri Baptist Medical Center. “These data add to the growing body of evidence that

supports the role of Gilenya as an efficacious treatment option for patients previously treated with other DMTs."

Novartis is also presenting an analysis of five studies assessing Gilenya (0.5 mg, 1.25 mg and 5.0 mg) in more than 4,000 patients with relapsing-remitting MS across diverse geographies, including the United States, Canada, Europe and Japan. Patients treated with Gilenya 0.5 mg for duration of six months to two years showed a reduction in ARR by nearly 50% vs placebo and interferon beta-1a IM [FREEDOMS: 54% $p<0.05$; FREEDOMS II: 48% $p<0.05$; TRANSFORMS: 52% $p<0.05$]. Gilenya 0.5 mg also increased the proportion of patients who remained free from relapse during the study period when compared to placebo [FREEDOMS: 70.4% to 45.6%] and to interferon beta-1a IM [TRANSFORMS: 82.6% to 69.3%]. The proportion of patients who were relapse-free at two years in the FREEDOMS II study has not yet been reported.

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 breastfeed, 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 or visit www.gilenyapregnancyregistry.com for more information.

Tell your doctor about all your medical conditions, including if you had or now have an irregular or abnormal heartbeat; history of stroke or warning stroke; 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.

For full Prescribing Information and the Medication Guide log onto www.pharma.us.novartis.com.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “are being presented,” “is also presenting,” 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 submitted or approved for any additional indications or labeling in any market, or at any particular time. 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; 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

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