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Relapsing MS patients more satisfied with Novartis oral drug Gilenya® than standard injectable therapies, according to new study results at CMSC

May 30, 2013

- -- At six months, adjusted mean treatment satisfaction scores increased by a statistically significant 20.4 with Gilenya vs. 2.9 with injectable disease modifying therapies1
- -- In one of the largest studies of its kind, overall patient treatment satisfaction with once-daily Gilenya exceeded 80 on a 100-point TSQM scale1

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EAST HANOVER, N.J., May 30, 2013 /PRNewswire/ -- People with relapsing multiple sclerosis (MS) reported greater treatment satisfaction after starting the oral treatment Gilenya® (fingolimod) vs. switching to, or staying on, injectable interferon beta or glatiramer acetate, according to new study data presented at the 2013 Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC) in Orlando, Fla.[1]

The US phase IV randomized, multi-center, open-label study, called EPOC (Evaluate Patient OutComes), evaluated treatment satisfaction among more than 1,000 patients.[1,2] The study compared Gilenya to interferon beta or glatiramer acetate using a 100-point scale based on the Treatment Satisfaction Questionnaire for Medication (TSQM),[1] a validated tool that measures patient satisfaction with medical treatments.[3] A higher TSQM score indicates higher satisfaction.

At six months, adjusted mean treatment global satisfaction subscale scores (a measure of the overall level of satisfaction with a medication that patients are taking) were 80.4 for Gilenya vs. 61.1 for the injectable disease modifying therapies (DMTs), an increase from baseline by 20.4 vs. 2.9, respectively.[1] The mean difference between the two scores was a statistically significant 17.5 ($p<0.001$).[1]

"Patient satisfaction is critical for the management of chronic conditions like MS," said Christopher LaGanke, MD, of North Central Neurology Associates in Cullman, Ala., and a study investigator. "These treatment satisfaction results are meaningful to clinicians and add important real-world insight to the established clinical trial evidence we already have for fingolimod."

A separate analysis of EPOC indicated that the overall incidence of infection was similar among patients taking Gilenya and patients taking standard injectable DMTs – consistent with results from previous studies.[4] The analysis also found no observed relationship between lymphocyte counts and infection rates.[4]

"We led a revolution in MS treatment two years ago with the introduction of the first oral disease modifying

therapy," said Dr. Timothy Wright, Global Head Development, Novartis Pharmaceuticals AG. "We are committed to continuing to provide critical insights to help physicians understand the role of Gilenya."

With more than two years on the market, Gilenya is approved in 72 countries and more than 63,000 patients worldwide have been treated with Gilenya.[5] This includes both clinical trials and patients prescribed Gilenya.[5]

About Gilenya

Gilenya is the first oral disease modifying therapy (DMT) approved to treat relapsing forms of MS[6] and the first in a class of compounds called sphingosine 1-phosphate receptor (S1PR) modulators.[6,7] The mechanism by which fingolimod exerts therapeutic effects in multiple sclerosis is unknown, but may involve reduction of lymphocyte migration into the central nervous system.[6,7] 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).[7,8]

Gilenya is the only oral DMT for relapsing forms of MS with proven and consistent efficacy across two pivotal trials, including a head-to-head study (interferon beta-1a IM).[9,10] In a two-year study, Gilenya reduced annualized relapse rate by 54 percent ($p<0.001$) when compared to placebo.[10] In addition, Gilenya showed a 30 percent reduction in the risk of three-month confirmed disability progression ($p=0.02$, key secondary endpoint) compared to placebo.[10] However, in a separate one-year study, there was no significant risk reduction of disability progression between Gilenya and interferon beta-1a IM. Gilenya reduced annualized relapse rate by 52 percent ($p<0.001$) compared to interferon beta-1a IM in a one-year study.[9] A two-year pivotal clinical trial has shown that the majority of patients who started on Gilenya stayed on therapy compared to placebo (81.2 percent vs. 72.5 percent).[10] Gilenya is licensed from Mitsubishi Tanabe Pharma Corporation.

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.

Please see full Prescribing Information for Gilenya:
http://www.pharma.us.novartis.com/cs/www.pharma.us.novartis.com/product/pi/pdf/gilenya.pdf

Disclaimer

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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 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 129,000 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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