Novartis data show Gilenya® had significantly greater patient retention compared to iDMTs in relapsing-remitting MS

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- - Data demonstrate at 12 months, 81% of patients started on fingolimod stay on therapy vs. 29% started on injectable disease-modifying therapies (iDMTs)(1)
- - Injectable disease-modifying therapies are frequently used first-line for MS despite evidence of sub-optimal patient adherence(2),(3)

EAST HANOVER, N.J., June 3, 2016 /PRNewswire/ -- Novartis today announced data from a randomized, prospective, Phase IV, open-label study that demonstrated patient retention rate with Gilenya® (fingolimod) was significantly higher at 12 months than with injectable disease-modifying therapies in patients with early relapsing-remitting multiple sclerosis (RRMS), 81% vs. 29% respectively[1]. Compared to injectable disease-modifying therapies, Gilenya also improved clinical and MRI outcomes and was associated with greater patient satisfaction[1]. The findings were presented for the first time in the US at the 2016 Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC) in National Harbor, MD, June 1-4, 2016.

While injectable disease-modifying therapies typically are used as first-line therapies for RRMS, research suggests the requirement for injections may reduce patient adherence[2,3]. The Prospective, Randomized, active-controlled, open-label study to Evaluate patient retention of Fingolimod versus approved first-line disease-modifying therapies in adults with Relapsing-remitting Multiple Sclerosis (PREFERMS) was the first large randomized study of treatment retention comparing fingolimod 0.5 mg with injectable disease-modifying therapies (interferon ß or glatiramer acetate) over a period of 12-months[1]. Safety outcomes for all treatments were consistent with the respective US Prescribing Information.

"Encouraging patients to stay on treatment is particularly important in relapsing MS, given lack of active management can lead to disability progression," said PREFERMS lead investigator Bruce Cree, MD, Associate Professor, University of California San Francisco School of Medicine. "Our findings suggest that use of fingolimod may improve therapeutic retention compared to injectable disease-modifying treatments that are often times used as first-line therapies."

Study Design[1]
PREFERMS was a 12-month, Phase IV, open-label, active-controlled, randomized, multicenter study conducted at 117 sites in the US. At enrollment, patients with RRMS were treatment-naïve or had received only one injectable disease-modifying therapy class (IFNβ-1a, IFNβ-1b or glatiramer acetate). A total of 875 patients were randomized (1:1) to Gilenya 0.5 mg or to a pre-selected injectable disease-modifying therapy, and followed up quarterly for 12 months. After a minimum of 3 months of treatment, a single on-study treatment switch was allowed, however, switches due to efficacy or safety were allowed at any month following randomization. The primary endpoint was to compare the patient retention on randomized treatment over 12 months.

Efficacy Findings

Of the 861 patients (98.4%) who completed the study (full analysis set), 477 (55.4%) completed the study while still receiving the randomized treatment[1]. At the primary endpoint, patient retention with Gilenya was 81.3% (352 of 433 Gilenya patients) versus 29.2% (125 of 428 injectable disease-modifying therapy patients) with injectable disease-modifying therapy ($p<0.0001$) at 12 months[1].

Safety Findings

During the randomized open-label treatment phase, the overall rate of adverse events (AEs) per patient-year were higher with injectable disease-modifying therapies (7.001) versus Gilenya (4.008) and the rate of AEs per patient-year leading to treatment discontinuation were 0.540 with injectable disease-modifying therapies versus 0.112 with Gilenya[1]. Most adverse events were mild or moderate in severity[1].

The rates of serious AEs per patient-year were 0.083 for Gilenya and 0.076 for injectable disease-modifying therapies[1]. There were 3 deaths in the study, including one patient from each the Gilenya and injectable disease-modifying therapy groups and one patient who entered the screening process but not the randomization phase. None of the deaths were attributed to the study medications[4]. Higher rates of treatment discontinuation in the injectable disease-modifying therapy group than in the Gilenya group were mainly attributable to higher rates of injection-site conditions, influenza-like symptoms and fatigue[1].

These data were also presented in April 2016 at the 68th Congress of the American Academy of Neurology in Vancouver, Canada.

About Multiple Sclerosis

Multiple sclerosis, a chronic disease of the central nervous system, affects around 400,000 people in the US[4]. Approximately 85 percent of people with MS have relapsing-remitting MS, where the immune system attacks healthy tissue[5]. This form of MS is a potentially debilitating condition characterized by relapses with worsening neurological function, followed by periods of remission where patients partially or fully recover, during which the disease remains stable[6].

About Gilenya

Gilenya is the first once-a-day pill approved to treat relapsing forms of multiple sclerosis (RRMS). Approved for first-line use, Gilenya is a Disease Modifying Therapy (DMT) that offers freedom from injections, which may fit many patients' lifestyles. Gilenya helps slow down the physical problems caused by RRMS and decreases the frequency of MS flare-ups (relapses).

Gilenya is the most prescribed oral once-daily DMT. In the US, more than 64,000 patients have been exposed to Gilenya. Worldwide, more than 148,000 patients have been treated with Gilenya in clinical trials and the post-marketing setting, with more than 316,000 years of real-world experience[7].

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), including a heart finding called prolonged QT as seen on an ECG, or if you take medicines that change your heart rhythm. Do not take Gilenya if you are allergic to fingolimod or any of the other ingredients.

Gilenya may cause serious side effects such as:

- Slow heart rate, especially after first dose. You will be monitored by a health care professional for at least 6 hours after your first dose. Your pulse and blood pressure will be checked hourly. You'll get an ECG before and 6 hours after your first dose. If any heart problems arise or your heart rate is still low, you'll continue to be monitored. If you have any serious side effects, especially those that require treatment with other medicines, or if you have certain types of heart problems, or if you're taking medicines that can affect your heart, you'll be watched overnight. If you experience slow heart rate, it will usually return to normal within 1 month. Call your doctor, or seek immediate medical attention if you have any symptoms of slow heart rate, such as feeling dizzy or tired or feeling like your heart is beating slowly or skipping beats. Symptoms can happen up to 24 hours after the first dose. Do not stop taking Gilenya without consulting with your doctor. Call your doctor if you miss 1 or more doses of Gilenya—you may need to repeat the 6-hour monitoring.
- 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. Gilenya may decrease the way vaccines work in your body, especially the chicken pox vaccine. 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, vomiting, or headache accompanied by fever, neck stiffness, sensitivity to light, nausea, and/or confusion. These may be symptoms of meningitis.
- Progressive multifocal leukoencephalopathy (PML). PML is a rare brain infection that usually leads to death or severe disability. If PML happens, it usually happens in people with weakened immune systems. It is important that you call your doctor right away if you have any new or worsening medical problems that have lasted several days, including problems with thinking, eyesight, strength, balance, weakness on 1 side of your body, or using your arms and legs.
- Macular edema, a vision problem that can cause some of the same vision symptoms as an MS attack (optic neuritis), or no symptoms. If it happens, 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.
- Swelling and narrowing of the blood vessels in your brain. A condition called PRES (Posterior reversible encephalopathy syndrome) has occurred rarely in patients taking Gilenya. Symptoms of PRES usually get better when you stop taking Gilenya. However, if left untreated, it may lead to a stroke. Call your doctor right away if you experience any symptoms, such as sudden headache, confusion, seizures, loss of vision, or weakness.
- 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.
- A type of skin cancer called basal cell carcinoma (BCC). Talk to your doctor if you notice any skin nodules (shiny, pearly nodules), patches or open sores that do not heal within weeks. These may be signs of BCC.

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. For more information, contact the Gilenya Pregnancy Registry by calling Quintiles at 1-877-598-7237, by e-mailing gpr@quintiles.com, or by going to www.gilenyapregnancyregistry.com.

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 repeated fainting; a fever or infection, or if you are unable to fight infections due to a disease or are taking medicines that lower your immune system, including corticosteroids, or have taken them in the past; eye problems; diabetes; breathing or liver problems; or uncontrolled high blood pressure. Also tell your doctor if you have had chicken pox or have received the chicken pox vaccine. Your doctor may test for the chicken pox virus, and you may need to get the full course of the chicken pox vaccine and wait 1 month before starting Gilenya.

If you take too much Gilenya, call your doctor or go to the nearest hospital emergency room right away.

Tell your doctor about all the medicines you take or have recently taken, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Tell your doctor if you have been vaccinated within 1 month before you start taking Gilenya. You should not get certain vaccines, called live attenuated vaccines, while taking Gilenya and for at least 2 months after stopping Gilenya treatment.

The most common side effects with Gilenya were headache, abnormal liver tests, diarrhea, cough, flu, sinusitis, back pain, abdominal pain, and pain in arms or legs.

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 words such as "suggests," "can," "suggest," "may," "potentially," "will," or similar terms, 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 are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking 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 be commercially successful in the future. In particular, management's expectations regarding Gilenya could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety, quality or manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. 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

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 and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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List of links present in page

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