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Novartis therapy Gilenya™ reduced the risk of MS disability progression regardless of treatment history or disease severity, new analysis shows

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- Gilenya delayed the progression of disability both for patients who were previously treated for their MS and for patients who had not received prior treatment
- 11 scientific abstracts on Gilenya efficacy and safety will be presented at the American Academy of Neurology annual meeting
- Gilenya, first oral in a new class of drugs called S1P receptor modulators, is approved in more than 35 countries including US, Canada and Germany

East Hanover, NJ, April 11, 2011 – A new analysis demonstrated that Gilenya™ (fingolimod) reduced the risk of disability progression in patients with relapsing-remitting multiple sclerosis (RRMS), regardless of treatment history. This analysis of the phase III two-year FREEDOMS study is one of 11 abstracts on Gilenya being presented at the 63rd annual meeting of the American Academy of Neurology (AAN).

“In developing Gilenya, Novartis initiated a large clinical trial program that would provide the MS community with robust data to define the efficacy and safety profile of this oral treatment for relapsing forms of MS,” said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. “Our scientific presence at AAN is evidence of our commitment to continued research and ongoing reporting of clinical information to physicians and patients."

The primary endpoint for the two-year FREEDOMS study was relapse rate, in which Gilenya reduced relapses by 54% compared to placebo ($p<0.001$). In a key secondary endpoint, Gilenya showed a 30% reduction ($p<0.05$) in the risk of 3-month confirmed disability progression as compared to placebo over two years.

The FREEDOMS analysis presented this week at AAN showed that 0.5 mg Gilenya-treated patients who were new to therapy (n=493) had a 37% reduction in the risk of 3-month confirmed disability progression compared to placebo (HR: 0.63; 95% CI: 0.41-0.95) while those previously treated with alternate therapies (n=350) Gilenya 0.5 mg led to a 30% reduction in risk (HR: 0.70;95% CI:0.43-1.14). Consistent favorable effects on disability progression were observed for Gilenya-treated patients compared to placebo for subgroups defined by age, gender, disease severity as defined by EDSS score, relapse activity prior to study, magnetic resonance imaging (MRI) lesion burden or lesion activity at the time of the start of the study.

"These data provide deeper insights into the effect of Gilenya in significantly reducing MS disability progression across the broad range of patient subpopulations that this analysis evaluated," said Virginia Devonshire, MD, Director of the University of British Columbia MS Clinic and a FREEDOMS trial investigator.

Gilenya, licensed from Mitsubishi Tanabe Pharma Corporation, is the first oral treatment in a new class of drugs called sphingosine 1-phosphate receptor (S1PR) modulators. Approved in more than 35 countries including US, Canada and Germany, 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), which includes the brain and spinal cord. As shown in animal models, Gilenya stops many of the white blood cells (lymphocytes) from leaving the lymph nodes. Exactly how Gilenya works in MS is unknown, but it is thought that it results in fewer white blood cells entering the CNS to attack and damage the myelin sheath. If Gilenya treatment is stopped for any reason, the number of white blood cells circulating in the body increases over the first few days and gradually returns to normal within 1 to 2 months.

About Gilenya
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
Gilenya may cause serious side effects such as:

Slow heart rate, especially about 6 hours after the 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 observe 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 you 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 your blood. This will usually go back to normal within 2 months of stopping Gilenya. A doctor may do a blood test before you start Gilenya. Increased risk of infection was seen with Gilenya doses greater than the recommended dose. 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. A doctor should test a patient's vision before they start Gilenya; 3 to 4 months after a patient starts Gilenya; and any time they notice vision changes. Vision problems may continue after macular edema has gone away. Risk of macular edema may be higher if a patient has diabetes or has had an inflammation of your 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.

Patients should tell their doctor about all their medical conditions, including if they have 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 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.

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

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.

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.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by terminology such as “risk,” “will,” “would,” “commitment,” or similar expressions, or by express or implied discussions regarding potential future 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. 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; government, industry and general public pricing pressures, including governmental reimbursement issues; competition in general; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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.

Novartis Pharmaceuticals Corporation
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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. 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 119,000 full-time-equivalent associates (including 16,700 Alcon associates) and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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Central media line :

+41 61 324 2200

Eric Althoff
Novartis Global Media Relations
Phone: +41 61 324 7999
Mobile: +41 79 593 4202
Email: eric.althoff@novartis.com

Maureen Byrne
Novartis Pharmaceuticals Corporation
Phone: 862 778 1518
Mobile: 973 714 0063
Email: maureen.byrne@novartis.com

Email: media.relations@novartis.com

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5. http://www.novartis.com
6. mailto:eric.althoff@novartis.com
7. mailto:maureen.byrne@novartis.com
8. mailto:media.relations@novartis.com