

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****FDA advisory committee unanimously recommends approval of Novartis investigational treatment FTY720 to treat relapsing remitting MS**

- *Committee voted in favor of approval of FTY720 (fingolimod), as treatment in relapsing remitting multiple sclerosis, affirming the drug's positive benefit/risk profile*
- *FTY720, potentially first in a new class of MS therapy, represents a significant advance as an efficacious oral treatment for people with relapsing remitting MS*
- *Committee recommended post marketing collection of additional safety data and evaluation of a lower dose*

**Basel, June 10, 2010** – Today, an advisory committee of the US Food and Drug Administration (FDA) recommended approval of FTY720 (fingolimod) for the treatment of patients with relapsing multiple sclerosis, the most common form of the disease. The FDA has the option of seeking the advice of one of its advisory committees as it reviews and decides whether to approve a new treatment. The committee voted unanimously that FTY720 demonstrated substantial efficacy in treating relapsing remitting MS and that safety of the proposed 0.5 mg dose justified approval.

“This is an encouraging and important milestone for the MS community,” said Dr. Patricia O’Looney, Vice President, Biomedical Research at the National Multiple Sclerosis Society. “We believe that a treatment that reduces relapses and slows disability progression in a convenient oral formulation could encourage more people with MS to initiate treatment in the course of this life-long disease.”

The committee evaluated data from the largest clinical trial program ever submitted to the FDA as part of an MS new drug application. This study data provided evidence of superior efficacy of FTY720 over one of the most commonly prescribed treatments, interferon beta-1a IM (Avonex<sup>®</sup>), and to placebo, in reducing relapses and brain lesions (a measure of disease activity)<sup>1,2</sup>. In addition, the two-year placebo-controlled study showed FTY720 significantly delayed disability progression<sup>2</sup>. The advisory committee discussed monitoring parameters for the therapeutic use of FTY720 and also recommended post-marketing collection of additional safety data and evaluation of a lower dose.

“Novartis is pleased by the committee’s vote to recommend FDA approval of FTY720 as a treatment that has demonstrated substantial efficacy for relapsing remitting multiple sclerosis. The committee’s positive vote affirms the favorable benefit/risk profile of FTY720 and we will work closely with the FDA as it finalizes its review of our new drug application,” said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. “If approved, FTY720 will offer patients an effective treatment in the convenience of a pill and we look forward to making this innovative therapy available for people with MS.”

If approved, FTY720 would potentially be the first oral therapy for treating relapsing MS. FTY720 would be the first in a new class of therapies developed for relapsing MS called sphingosine1-phosphate receptor (S1PR) modulators, which work by retaining certain immune cells (lymphocytes) in the lymph nodes, preventing them from reaching the central nervous system and causing damage. This lymphocyte retention is reversible, allowing circulating lymphocytes to regain normal levels if treatment is stopped.

The FDA granted FTY720 priority review status in February 2010, reducing the standard 10-month review to six months. In May, the FDA extended the priority review period by three months to September 2010.

The safety profile of FTY720 has been well studied and includes more than 4,500 patient years of experience, with some patients in their seventh year of treatment. In Phase III studies FTY720-related adverse events included transient, dose-related, generally asymptomatic heart rate reduction and infrequent transient AV conduction block at treatment initiation, mild (1-3 mm Hg) blood pressure increase, macular edema (more common with 1.25 mg than the 0.5 mg target dose), and generally asymptomatic, reversible elevation of liver enzymes<sup>1,2</sup>.

The rates of infections overall, including serious infections, were comparable among treatment groups, although a slight increase in lung infections (primarily bronchitis) was seen in patients treated with FTY720. The number of malignancies reported across the two studies was small with comparable rates between the FTY720 and control groups<sup>1,2</sup>.

Multiple sclerosis 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 up to 2.5 million people worldwide. The most common form of the disease, relapsing MS, is characterized by exacerbations or “flare-ups” interspersed with periods of disease remission. Typically, MS strikes in early adulthood between the ages of 20 and 40, and affects women twice as frequently as men.

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### **References**

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