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MEDIA RELEASE · COMMUNIQUE AUX MEDIAS · MEDIENMITTEILUNG

FTY720, a novel once-daily oral medication, shows promising results in treatment of multiple sclerosis

- *Over two million people worldwide are estimated to suffer from multiple sclerosis, which is the leading cause of neurological disability in young adults¹*
- *Currently approved therapies have only limited clinical effect and require frequent injections*

Basel, Switzerland, June 21, 2005 – Phase II data presented today at the 15th European Neurological Society (ENS) meeting in Vienna showed that FTY720, a novel oral medication for the treatment of multiple sclerosis (MS), reduced the rate of clinical relapses by more than 50% and inflammatory disease activity as measured by magnetic resonance imaging (MRI) by up to 80% over six months compared to placebo.

Benefits of FTY720 therapy were seen as soon as after two months of treatment and continued to increase over the six month treatment period compared to placebo. Over 90% of patients completed the study.

“FTY720 has shown a significant and consistent effect on both clinical relapses and MRI measures in just six months. With its novel mode of action and the added benefit of an oral formulation taken once daily, further clinical development of FTY720 might have a major impact on the way we treat MS in the future. We hope that the magnitude of benefits shown in phase II will be confirmed in the larger scale phase III study program,” said Professor Ludwig Kappos, MD, Department of Neurology, University Hospital, Basel, Switzerland.

Based on the positive Phase II study results, Novartis is currently discussing with regulatory authorities the FTY720 Phase III program which is expected to be launched in the fourth quarter of 2005 involving centers in North America and Europe.

MS is the most common chronic, disabling disease of the central nervous system affecting young people in the prime of their lives. It is the leading cause of neurological disability in young adults.¹ Currently marketed MS therapies have only limited clinical effect with an average reduction in relapse rates of about 30% based on two year studies.

Furthermore, they require frequent injections ranging from daily to weekly. Patient surveys show that - second to limited efficacy - one of the main obstacles to initiating and maintaining MS therapy long-term are the patient's fear of needles, the inconvenience of injecting and side effects associated with current therapies, such as flu-like symptoms and injection site reactions.²

The six-month results are from a large double-blind, placebo-controlled, Phase II study conducted at 32 centers in 11 countries (Europe and Canada) in 281 patients with relapsing

MS, the most common form of the disease. The study evaluated the effect of FTY720 on disease activity as measured by MRI and clinical relapses as well as its tolerability and safety over a treatment period of six months. Study participants were randomized in equal numbers to receive either FTY720 1.25 mg, FTY720 5 mg, or placebo.

FTY720 phase II study results³

Relapse rates were reduced by 55% in the FTY720 1.25mg group ($p=0.009$) and 53% in the FTY720 5mg group ($p=0.014$) compared to placebo. Time to first confirmed relapse was significantly prolonged in both FTY720 groups ($p=0.007$ in FTY720 1.25 mg, $p=0.012$ in FTY720 5 mg) and 86% of patients in both FTY720 treatment groups remained relapse-free over six months compared to 70% of patients on placebo ($p=0.007$ in FTY720 1.25 mg, $p=0.008$ in FTY720 5 mg).

Inflammatory disease activity as measured by the total number of gadolinium (Gd) enhancing T1 MRI lesions was reduced by up to 80 % ($p<0.001$ in FTY720 1.25 mg, $p<0.006$ in FTY720 5 mg) over six months of treatment. Furthermore, new disease activity as measured by new T2 MRI lesions was reduced by more than two thirds in both FTY720 doses ($p<0.001$) compared to placebo.

Effects on relapses and MRI were seen as soon as after two months of treatment and continued to increase over the six month treatment period compared to placebo. "These consistent effects on MRI and clinical outcomes with both treatment doses are very encouraging as this short-term study was primarily powered to detect effects on MRI lesions but not on clinical outcomes," concluded Professor Kappos.

FTY720 appeared to be generally well tolerated with 92% of patients completing the six-month treatment period and 98% of those patients volunteered to continue in the ongoing extension phase. Most frequently reported adverse events were related to non-serious infections (such as colds), gastrointestinal disorders (such as diarrhea and nausea), nervous system disorders (such as headaches) and respiratory disorders (such as short breath and cough). The overall incidence of adverse events was higher in the FTY720 5 mg group compared to the FTY720 1.25 mg and placebo groups.

FTY720 Phase III MS study program

These findings need to be confirmed in larger scale clinical studies of longer duration. As FTY720 is also being developed for use in renal transplantation, the US Food and Drug Administration (FDA) has asked Novartis to conduct an overall safety analysis of FTY720's transplantation safety database. As a result, the Phase III program in MS is expected to be launched in the fourth quarter of 2005 involving centers in North America and Europe.

"Novartis has been a leader in neuroscience for more than 50 years. FTY720 is important because it affirms our commitment to provide people with MS, their families and treating physicians with a long-awaited significant improvement in MS therapy," said Jörg Reinhardt, Global Head of Development.

About FTY720

FTY720 is a once-daily oral medication with a novel mode of action offering the potential of an innovative approach to MS treatment. It is the first sphingosine-1-phosphate (S1P) receptor modulator.

FTY720 differs from currently approved treatments because it is the only medication that binds the receptors of S1P, present on the surface of lymphocytes, which are a subpopulation of white blood cells. In MS, lymphocytes circulating in the central nervous system (e.g. the brain and spinal cord) attack the myelin sheath that surrounds and protects nerve fibers (axons) which are responsible for transmitting nerve signals to other parts of the body.

As a consequence of receptor binding, the lymphocytes can no longer respond to the molecule that signals them to circulate to sites of inflammation in the body and they stay in the lymph nodes. However, the lymphocytes remain functional and may still be activated within the lymph nodes as part of the immune response.

FTY720 has been developed by Novartis Pharma and licensed from Mitsubishi Pharma Corporation.

About Multiple Sclerosis

Over two million people worldwide are estimated to suffer from multiple sclerosis, which is the leading cause of neurological disability in young adults.¹ MS is the most common inflammatory and neurodegenerative disorder of the central nervous system, including the brain, spinal cord and optic nerves.⁴ It is usually diagnosed between age 20 and 40 and is twice as common in women as men.¹ A patient can go for months, years or even decades without a relapse.⁵ However about 50% of sufferers need a cane for walking up to 100 meters after 15 years.⁶

MS typically presents in relapsing forms. The relapsing-remitting (RRMS) course is the most common form of the disease. Patients suffer acute self-limiting attacks (relapses) of neurological dysfunction followed by complete or incomplete remission in function. Over time, transmission of electrical nerve impulses is disrupted, nerve cells are destroyed, and patients experience symptoms ranging from fatigue, tingling, numbness and blurred vision to poor muscle control with partial or complete paralysis, speech or mental impairment.

About 50% of patients advance to the secondary progressive (SPMS) course within 10 years.⁶ MS has a significant impact on the patient's social activities, employment and overall quality of life.

This release contains certain forward-looking statements relating to Novartis' business, which can be identified by the use of forward-looking terminology such as "long-awaited breakthrough," "the first of several new and exciting," "innovative approach," or similar expressions, or regarding potential future revenue from FTY720. Such forward-looking statements reflect the current views of Novartis regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with FTY720 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that FTY720 will be approved for any additional indications or labeling in any market. Nor can there be any guarantee of potential future sales of FTY720. Neither can there be any guarantee regarding the long-term impact of a patient's use of FTY720. In particular, management's expectations regarding commercialization of FTY720 could be affected by, among other things, unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; Novartis' ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures, and other risks and factors referred to in Novartis' 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

Novartis has been a leader in the neuroscience area for more than 50 years, having pioneered early breakthrough treatments for Alzheimer's disease, Parkinson's disease, attention deficit/hyperactivity disorder, epilepsy, schizophrenia and migraine. Novartis continues to be active in the research and development of new compounds, is committed to addressing unmet medical needs and to supporting patients and their families affected by these disorders.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2004, Novartis' businesses achieved sales of USD 28.2 billion and a net income of USD 5.8 billion. Novartis invested approximately USD 4.2 billion in R&D. Headquartered in Basel, Switzerland, the Novartis group of companies employ about 81,400 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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¹ Multiple Sclerosis International Federation (http://www.msif.org/en/ms_the_disease/quick_facts.html)

² Primary market research TNS healthcare 8/04, NOP World Health Report on MS 11/04.

³ FTY720 in relapsing MS: Results of a double blind placebo controlled trial with a novel oral immunomodulator. Clinical Abstract of data presented at the 15th European Neurological Society meeting, Vienna, June 18-22, 2005.

⁴ Multiple Sclerosis International Federation (http://www.msif.org/en/ms_the_disease/index.html)

⁵ Multiple Sclerosis International Federation (http://www.msif.org/en/ms_the_disease/types_of_ms.html)

⁶ Weinshenker BG. Natural history of multiple sclerosis. Ann Neurol 1994, 36: S6-S11.