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Extavia® approved in European Union for treatment of multiple sclerosis, first in planned portfolio of therapies from Novartis

- *Extavia is Novartis brand for interferon beta-1b – an established therapy with more than 700,000 patient-years' experience to date¹*
- *Launch of Extavia for early and relapsing forms of multiple sclerosis (MS) planned for US and Europe in first half of 2009*
- *Novartis committed to MS through extensive research and development programs, including novel oral therapy FTY720 currently in Phase III trials*
- *MS, a devastating disease causing progressive disability, affects an estimated 2.5 million people worldwide, including many young adults²*

Basel, May 26, 2008 — The European Commission has approved Extavia® (interferon beta-1b) for the treatment of early and relapsing forms of multiple sclerosis (MS) – the first in a new portfolio of medicines from Novartis that is planned to include both established treatments and innovative therapies for patients with MS.

Extavia is the Novartis branded version of interferon beta-1b, a first-line disease-modifying therapy injected every other day for the treatment of MS. Interferon beta-1b has been available globally for more than 13 years and is supported by more than 700,000 patient-years of experience¹.

Formerly known as NVF233, Extavia is the same medicine as Betaferon®/Betaseron®, which is marketed by Bayer-Schering and was the first beta interferon treatment for MS. Novartis gained rights to its own branded version of this medicine in agreements with Bayer-Schering related to the acquisition of Chiron.

“Novartis is committed to MS and to providing effective treatments for patients with this disease,” said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. “The approval of Extavia means we are able to offer the MS community a current standard of care while preparing for the introduction of innovative therapies such as FTY720.”

Novartis also recently filed for approval of interferon beta-1b with the US Food and Drug Administration. Launches in the US and EU are planned for the first half of 2009, in line with an agreement with Bayer-Schering that established the opportunity for Novartis to introduce its own branded version of interferon beta-1b.

By the end of 2009, Novartis also plans to file for approval of the innovative oral therapy FTY720 (fingolimod). Results of an ongoing Phase II study extension presented in April show sustained benefits in patients with relapsing MS after three years of treatment with FTY720. Data showed that 68-73% of patients in the study remained free from relapses after three years' continuous treatment³.

A number of other compounds for treating MS are also in early stage development by Novartis.

Multiple sclerosis is the most common disorder of the central nervous system in young adults². It is a progressive and debilitating disorder caused by the destruction of myelin, which helps neurons carry electrical signals in the brain. MS causes problems with muscle control and strength, vision, balance, sensation and cognitive function². MS typically presents in relapsing forms involving acute self-limiting attacks of neurological dysfunction (or “relapses”) followed by complete or partial restoration of functions⁴.

In the EU, Extavia is approved for patients with relapsing-remitting MS, the most common form of the disease involving relapses followed by complete or partial restoration of function, and for a steadily worsening form of the disease known as secondary progressive MS with relapses.

In addition, Extavia is approved to treat patients with early MS who:

- Have experienced a single episode involving loss of myelin (or “demyelinating event”)
- Have an active inflammatory process that is severe enough to need treatment with intravenous corticosteroids, if alternative diagnoses have been excluded
- Are at high risk of developing clinically definite MS.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “plans”, “will”, “should” or similar expressions, or by express or implied discussions regarding potential new indications, labeling or regulatory filings or approvals for Extavia® or regarding potential future revenues from Extavia®. Such forward-looking statements reflect the current views of the management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Extavia® to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Extavia® will be approved for any additional indications or labeling by the European Commission or that Extavia will be approved for any indications in any additional markets. There can also be no guarantee that Extavia® will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Extavia® could be affected by, among other things, introduction of new MS therapies, unexpected regulatory actions or delays or government regulation generally or involving Extavia®, interferon beta-1b; 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; competition in general; government, industry and general public pricing pressures, 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.

About Novartis

Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group’s continuing operations (excluding divestments in 2007) achieved net sales of

USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- 1 Data on file. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc; 2007.
- 2 Multiple Sclerosis International Federation at www.msif.org Accessed 15 May 2008.
- 3 Comi G et al. Oral FTY720 (fingolimod) in patients with relapsing multiple sclerosis. 3-year extension shows sustained low relapse rate and MRI activity. Abstract presented at 60th annual meeting of American Academy of Neurology, Chicago, 12-19 April 2008.
- 4 National Multiple Sclerosis Society at www.nationalmssociety.org, Accessed 15 May 2008.

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