Novartis suspends US marketing and sales of Zelnorm® in response to request from FDA

- Retrospective analysis of pooled clinical trial data shows numerical imbalance in cardiovascular events in patients taking Zelnorm compared to those on placebo

- FDA asks Novartis to suspend marketing and sales to permit further discussion of benefits and risks of Zelnorm

- Novartis believes Zelnorm provides important benefits for appropriate patients suffering from irritable bowel syndrome with constipation

- Discussions ongoing with FDA to evaluate best way to continue to make Zelnorm available to appropriate US patients

East Hanover, NJ, March 30, 2007 – Novartis is complying with a request from the Food and Drug Administration (FDA) to suspend US marketing and sales of Zelnorm® (tegaserod maleate), a treatment for irritable bowel syndrome (IBS) with constipation and chronic constipation.

This action has been taken after Novartis notified the FDA about a retrospective analysis of data from more than 18,000 patients in the clinical trial database. This was the result of an ongoing review involving a number of health authorities including the FDA.

A small (but not statistically significant) imbalance in cases of angina pectoris was recorded and included in the US label when Zelnorm was approved in 2002. A recent analysis of the entire clinical database revealed a statistically significant imbalance in the incidence of cardiovascular ischemic events in patients taking Zelnorm compared to those taking placebo. These events included myocardial infarction, stroke, and unstable angina pectoris.

The data, which were reviewed by independent experts, showed that events occurred in 13 out of 11,614 patients treated with Zelnorm (0.11%), compared to one case in 7,031 placebo-treated patients (0.01%). All patients affected had pre-existing cardiovascular disease and/or CV risk factors.

The rate of cardiovascular ischemic events seen in Zelnorm-treated patients in controlled trials corresponds approximately with the expected rates for such events in the general population.

“My review of the data suggested that a causal relationship is unlikely between tegaserod and the rare cardiovascular ischemic events observed in clinical trials,” said Jeffrey L. Anderson, MD, Professor of Internal Medicine at the University of Utah and Associate Chief, Cardiology Division, LDS Hospital in Salt Lake City, UT – an independent cardiologist who reviewed the
data. “Furthermore, the data did not show any consistent pattern of event type, time to event or dose relationship in tegaserod-treated patients.”

Multiple studies do not suggest any constrictive effects of Zelnorm on coronary arteries.

An estimated 12 million Americans suffer from the painful and disruptive symptoms of IBS with constipation. Many have symptoms for five to 10 years, which trigger missed work-days and often prevent them from participating in everyday activities with their family and friends.

“Zelnorm provides unique benefits to patients by treating the multiple symptoms of abdominal pain, bloating and constipation that are associated with IBS with constipation,” said Stephen Cunningham, MD, Vice President and Head of US Clinical Development and Medical Affairs at Novartis Pharmaceuticals Corporation. “Although we have complied with the FDA’s request and are collaborating with the agency, we continue to believe that Zelnorm provides important benefits for appropriate patients.”

Nevertheless, Novartis has suspended the marketing, sales and distribution of Zelnorm in response to the FDA’s request, so that public discussion and an Advisory Committee meeting can take place to determine the risks and benefits of this medicine.

Novartis and the FDA will communicate this information to physicians and patients, and will discuss the best way to continue to make Zelnorm available to appropriate patients, including through a Treatment IND. Patients taking Zelnorm are being advised to consult their physicians. For additional information regarding Zelnorm, call the Novartis Customer Interaction Center at 888-NOW-NOVA (888-669-6682).

Consistent with the decision to suspend marketing and sales, Novartis is asking US suppliers to return product to the company. Patients can return any unused and unexpired Zelnorm and Novartis will reimburse them their out-of-pocket costs.

Novartis is in discussion with health authorities in other countries where Zelnorm (also marketed as Zelmac) is available to determine next steps.

Zelnorm received FDA approval for the short-term treatment of women with IBS in the US on July 24, 2002. Zelnorm also received FDA approval for the treatment of men and women less than 65 years of age with chronic idiopathic constipation in the US on August 20, 2004.

Disclaimer
The foregoing release contains certain forward-looking statements that can be identified by terminology such as “will,” or similar expressions, or by express or implied discussions regarding potential future approvals to return Zelnorm/Zelmac to the market, or potential future sales of Zelnorm/Zelmac. Such forward-looking statements involve known and unknown risks, uncertainties or other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. There can be no guarantee that Zelnorm/Zelmac will be approved by the FDA or other health authorities for return to the market for any indication, or that Zelnorm/Zelmac will achieve any particular level of sales. In particular, management’s expectations regarding these matters could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results or results of data analysis, including additional analysis of existing clinical data and other data regarding patients’ experience with Zelnorm/Zelmac, or unexpected new clinical or other such data; competition in general; government, industry and general public pricing pressures; the ability to obtain or maintain patent or other proprietary intellectual property protection; as well as factors discussed in the
Company’s Form 20-F filed 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.

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Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG (NYSE: NVS), a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. In 2006, the Group’s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 101,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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