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## **Zelnorm® to be made available to US patients under restricted access program**

- *FDA approves limited treatment IND program for Zelnorm*
- *Novartis continues discussions with FDA to evaluate Zelnorm safety data and identify appropriate next steps*

**East Hanover, NJ, July 27, 2007** – In cooperation with the US Food and Drug Administration (FDA), Novartis has established a restricted access program for Zelnorm® (tegaserod maleate) so that patients in need of this medicine can be considered for treatment.

The program, called a treatment IND, is designed to help women in the US under 55 years of age who suffer from irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC), and for whom no other treatment has provided satisfactory relief and/or patients who had satisfactory improvement of their symptoms with prior Zelnorm treatment for IBS-C or CIC. Novartis and the FDA are moving forward with this program because of requests from physicians and patients following the marketing suspension of Zelnorm in March 2007.

Treatment INDs are generally used to allow restricted access to medications for patients in need if no comparable alternative drug or therapy is available to treat the disease. Patients given access through a treatment IND must meet specific FDA-approved criteria for enrollment.

Through the program, appropriate female patients with IBS-C or CIC who are assessed by their physicians as being in critical need can have access to Zelnorm for relief of the often painful and disruptive symptoms associated with these conditions. The program protocol and consent materials are designed to ensure that patients and physicians are fully informed of the potential risks and benefits of Zelnorm.

To be considered for access to Zelnorm through the treatment IND, patients must have IBS-C or CIC and meet the specific criteria in the treatment IND protocol. To become part of the treatment IND, patients should contact their physicians to inquire about the protocol and evaluate if they meet the criteria. For further details of the program's protocol, physicians can call 866-248-1348 or 888-669-6682 or go to [www.zelnorm.com](http://www.zelnorm.com).

For patients who do not meet the criteria of the treatment IND but have an urgent need for Zelnorm based on a life-threatening or severely debilitating condition, there may be an alternative option available through the FDA. Physicians may inquire about this potential access option by contacting Novartis at (888-NOW-NOVA) or the FDA CDER Division of Drug Information at 301-827-4570 or [www.fda.gov/cder](http://www.fda.gov/cder).

Novartis suspended US marketing and sales of Zelnorm as a result of an FDA request in order to permit further discussion of its benefit/risk profile. This decision was based on a review of a new retrospective analysis of pooled clinical trial data which showed that the incidence of cardiovascular ischemic events was higher in patients taking Zelnorm than in those taking placebo. However, no causal relationship between Zelnorm and cardiovascular ischemic events has been demonstrated.

Novartis has extensively studied Zelnorm and believes that this medicine provides important benefits for appropriate patients. Novartis is in discussions with the FDA to better understand the findings and to determine appropriate next steps.

IBS is a disorder characterized by abdominal pain or discomfort, bloating, and altered bowel function. An estimated 12 million Americans suffer from 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. Chronic constipation accounts for more than 5.7 million constipation-related outpatient visits each year, with more than 990,000 visits to emergency rooms and more than 580,000 to hospital outpatient facilities. It leads to more than 282,000 in-patient hospitalizations with constipation as the primary diagnosis.

### **Disclaimer**

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as “to be,” “continues,” “can have,” “may,” “believes” or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Zelnorm. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any future regulatory filings will satisfy regulatory requirements regarding Zelnorm, that Zelnorm will be brought back to market in the the US or any additional market or that Zelnorm will reach any particular level of sales. In particular, management's expectations regarding Zelnorm could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analysis of clinical data, or unexpected new clinical data, as well as the additional risks and factors discussed in Novartis AG’s Form 20-F filed 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 described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document 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, cure 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. 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. Novartis is the only company with leadership positions in these areas. 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 100,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.pharma.us.novartis.com>.

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