March 30, 2007

Dear Health Care Professional:

Novartis is writing to inform you that at the request of FDA we are suspending marketing for Zelnorm® (tegaserod maleate) tablets due to Important Safety Information.

In clinical studies involving over 18,600 patients, there was a small imbalance that was statistically significant in the incidence of cardiovascular ischemic events [13 per 11,614 (0.11%) Zelnorm; 1 per 7,031 (0.01%) placebo (p = 0.024)]. These events included myocardial infarction, unstable angina pectoris, and stroke.

All patients affected had pre-existing cardiovascular disease and/or CV risk factors. There was no pattern relative to the time of occurrence of these events and no association with dose. In addition, results obtained from multiple mechanistic studies do not suggest any arterial vasoconstrictive effect of tegaserod.

Novartis continues to believe in the benefits of Zelnorm and while Novartis is working with the FDA to evaluate additional actions required based on these data, a Treatment IND will be initiated to provide access to Zelnorm for appropriate patients.

Novartis Pharmaceuticals Corporation reiterates its commitment to the delivery of quality pharmaceutical products and is committed to ensuring the timely dissemination of new information that is important to physicians and patients. A brief statement and Q&A will be placed on the www.zelnorm.com website.
Novartis will be contacting you to arrange for the return of any product samples and vouchers in your possession. Patients can return unused and unexpired Zelnorm tablets and Novartis will reimburse them for their out-of-pocket costs. For full details on how and where to send unused and unexpired product, patients can contact the Novartis Customer Interaction Center at 888-NOW-NOVA (888-669-6682).

Healthcare professionals should continue to report all adverse events associated with the use of Zelnorm to Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, New Jersey, 07936, by phone (888) NOW-NOVA or (888-669-6682) or the internet at http://www.novartis.com.

Alternatively, this information may be reported to FDA’s MedWatch Reporting System by phone at 1-800-FDA-1088, by facsimile at 1-800-FDA-0178, by mail using the form 3500 at http://www.fda.gov/medwatch/index.html.

Sincerely,

Alan L. Bess, MD
Vice President
US Head Integrated Medical Safety

Stephen R. Cunningham, MD
Vice President
US Clinical Development and Medical Affairs