

FDA Approves Zelnorm as the First Rx Therapy For Chronic Constipation

4.5 Million Americans Suffer from Constipation Most of the Time

Basel, August 23, 2004 – Novartis Pharma AG announced that the U.S. Food and Drug Administration (FDA) today approved a supplemental indication for its pro-motility agent Zelnorm® (tegaserod maleate) for the treatment of chronic idiopathic constipation in male and female patients less than 65 years of age.

The new indication is supported by safety and efficacy data from the two largest and longest randomized, double-blind, placebo-controlled, multi-national Phase III clinical trials ever conducted in chronic constipation. The two three-month trials included more than 2,600 male and female patients. In addition, one of the studies included a 13-month extension safety study of 840 patients. Zelnorm was found to significantly increase the frequency of complete spontaneous bowel movements as well as to provide relief of the multiple symptoms of chronic constipation that patients complain about most, including straining, hard stool, incomplete evacuation, infrequent defecation, bloating and abdominal discomfort.

“Chronic constipation has a tremendous impact on patients’ lives, with nearly a million visits to emergency rooms every year, almost six million visits to doctors’ offices, and thousands of hospitalizations,” said Joerg Reinhardt, Head Development, Novartis Pharma AG. “We are very pleased the FDA has found Zelnorm safe and effective and has approved it for treatment of patients with chronic constipation. Novartis believes it will help bring relief to millions of patients.”

Zelnorm has been available since July 2002 as the first and only prescription medication proven to provide women with the relief of abdominal discomfort or pain, bloating and constipation associated with irritable bowel syndrome (IBS). IBS with constipation and chronic idiopathic (meaning not due to other diseases or drugs) constipation are both lower gastrointestinal dysmotility disorders.

About Constipation

Constipation, including that due to other diseases or drugs, is one of the leading gastrointestinal complaints in the United States, affecting nearly 18 percent of the population, or 37 million people. More than 4.5 million Americans report they are constipated most of the time. Chronic constipation, as a whole, accounts for more than 5.7 million constipation-related outpatient visits each year, with 990,994 to emergency rooms and 586,868 to hospital outpatient facilities. It leads to more than 282,000 in-patient hospitalizations with constipation as the primary diagnosis. Diagnosed cases of chronic constipation are evenly distributed across age groups and in both genders, although it is slightly more frequent in women.

A Need for New Therapies

“Chronic constipation can have a huge impact on the sufferer’s quality of life,” says Larry Schiller, M.D., Attending Physician, Baylor University Medical Center, Dallas, Texas. “In addition, many chronic constipation patients have expressed dissatisfaction with the efficacy and tolerability of standard treatment options including fiber, osmotic laxatives or bulking agents. Zelnorm offers a new proven option for these patients.”

A recent survey with 557 patients found that 47 percent of patients with chronic constipation were not completely satisfied with currently available therapies due to the efficacy of these agents (82 percent) and the safety and side effects (16 percent). More than half (52 percent) of respondents felt that chronic constipation adversely impacted their quality of life.

In another survey of 311 primary care physicians, 98 percent reported that constipation was at least somewhat bothersome to their patients, with 95 percent describing constipation as having some impact on patients’ quality of life. Furthermore, 60 percent of these physicians agreed that they do not have adequate products to treat patients with constipation, and 91 percent wished that better treatment options were available.

About Zelnorm

As a pro-motility agent, Zelnorm acts as an agonist at 5HT₄ (serotonin type 4) receptors in the GI tract and mimics the natural effects of serotonin by activating 5HT₄ receptors, which normalizes impaired motility in the GI tract, inhibits visceral sensitivity and stimulates intestinal secretion. Zelnorm treats dysmotility symptoms caused by chronic constipation and IBS with constipation.

Zelnorm is indicated for the short-term treatment of women with IBS whose primary bowel symptom is constipation. The safety and effectiveness of Zelnorm in men with IBS with constipation have not been established.

Zelnorm is also indicated for the treatment of patients less than 65 years of age with chronic idiopathic constipation. The effectiveness of Zelnorm in patients 65 years or older with chronic idiopathic constipation has not been established.

Overall, safety data is now available in more than 11,600 patients who have enrolled in clinical trials assessing Zelnorm’s safety and efficacy in various GI conditions.

In chronic constipation studies, the incidence of adverse events with Zelnorm was similar to that of placebo. The only adverse event reported more often with Zelnorm 6 mg twice-a-day than placebo was diarrhea (6.6 percent vs. 3 percent). Diarrhea rarely led to discontinuation of the study (0.9 percent). Typically, diarrhea was transient, lasting two days, and generally resolved without rescue medication or interruption of treatment. Data from the trial that incorporated a 13-month extension study showed Zelnorm to be generally safe and well tolerated long term.

In IBS with constipation clinical trials, tolerability to Zelnorm was similar to placebo. The only adverse event reported notably more often with Zelnorm than with placebo was diarrhea (9 percent vs. 4 percent). The majority of patients reporting diarrhea had a single episode and in most cases, diarrhea occurred in the first week of treatment. Typically, it resolved with continued therapy. Serious consequences of diarrhea, including hypovolemia, hypotension and syncope, have been reported in the clinical studies (0.04 percent) and during marketed use of Zelnorm. In some cases, these complications have required hospitalization for rehydration.

Zelnorm was developed by Novartis and is also known in some countries as Zelmac. It is approved in more than 55 countries for IBS with constipation. Zelnorm also is approved for use in chronic constipation in 10 countries, including Mexico and Latin America. Zelnorm is being studied as a potential treatment for other important GI motility disorders, including gastroesophageal reflux disease (GERD) and dyspepsia.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2003, the Group's businesses achieved sales of USD 24.9 billion and a net income of USD 5.0 billion. The Group invested approximately USD 3.8 billion in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 80,000 people and operate in over 140 countries around the world. For further information please consult <http://www.novartis.com>.

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