BAUSCH Health

Salix Announces FDA Approval of Xifaxan® 550 mg for the Treatment of IBS-D (Irritable Bowel Syndrome with Diarrhea)

May 27, 2015

Xifaxan® 550 mg is the first-and-only nonsystemic antibiotic approved for the treatment of IBS-D in adults

LAVAL, Quebec, May 27, 2015 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) announced that its wholly owned subsidiary, Salix Pharmaceuticals, Inc., has received approval from the U.S. Food and Drug Administration (FDA) for Xifaxan® 550 mg for the treatment of IBS-D in adults. The FDA approval of Xifaxan 550 mg is based on data from three phase 3 studies, TARGET 1, TARGET 2 and TARGET 3. Xifaxan 550 mg was studied in over 3,000 patients and demonstrated the efficacy and safety of repeat treatment following completion of a two-week course of treatment. A full course of Xifaxan 550 mg for IBS-D is available in a convenient 2 week pack of 42 pills.

"As a gastroenterologist who helps patients navigate the symptoms of IBS-D, I see the need for treatments that directly address those most bothersome, such as diarrhea and abdominal pain" said Dr. Mark Pimentel , director of the Gastrointestinal Motility Program and Laboratory at Cedars-Sinai in Los Angeles. "Today's approval gives a new option to these patients and providers."

As many as 35 million adult Americans may experience IBS, and 40% of people with IBS suffer from diarrhea-prominent symptoms that include urgency, loose, watery stools and abdominal pain.[i,ii,iii] Although millions suffer from the condition, current treatments for IBS-D are limited to products aimed at relieving individual symptoms (e.g., antispasmodics, anti-diarrheal agents, bulking agents, anti-flatulence agents) and fail to address the syndrome complex.

"The Xifaxan 550 mg approval gives patients access to a treatment that may alleviate their symptoms," said Dr. Costas H. Kefalas, president and member of the Board of Directors of the Digestive Disease National Coalition (DDNC). "This treatment is in line with the DDNC's mission to provide improved access to quality digestive health care."

The FDA approval was based on data from three clinical studies of more than 3,000 patients. Results of TARGET 1 and 2 showed patients treated with Xifaxan 550 mg achieved relief of the FDA composite endpoint (stool consistency and abdominal pain) versus placebo. TARGET 3 showed that patients who responded to treatment with Xifaxan 550 mg but experienced recurrent symptoms responded to repeat treatment in the FDA composite endpoint versus placebo.

"We are thrilled to offer patients this new option to manage their IBS-D symptoms," said Bill Forbes , PharmD, president, medical, R&D and chief development officer of Salix. "The FDA approval in IBS-D extends the reach of Xifaxan 550 mg beyond hepatic encephalopathy to a population greatly in need of a different treatment approach."

Xifaxan 550 mg offers a safety and tolerability profile comparable to placebo when used as directed.

Xifaxan is also FDA-approved to manage hepatic encephalopathy (550 mg). Recommended dosing for Xifaxan 550 mg for IBS-D is one 550 mg tablet three times a day for 14 days. Patients can take up to two additional courses if IBS-D symptoms recur in the future. Xifaxan 550 mg is currently available to patients.

About IBS
Irritable bowel syndrome (IBS) is a chronic gastrointestinal disorder characterized by recurrent abdominal discomfort or pain that is accompanied by at least two of the following: relief by a bowel movement, change in frequency of stool, or change in consistency in stool. IBS is thought to affect approximately 35 million Americans, is nearly twice as common in women as men, and is most commonly found in people under the age of 45. Forty percent of people with IBS suffer diarrhea-prominent symptoms.

About Gut Microbiota
The significant influence of the gut microbiota on human physiology, functioning and health has brought about a paradigm shift in understanding the pathophysiology of many human diseases, including IBS. Recent findings suggest that some IBS patients may have an alteration in their gastrointestinal flora.

About XIFAXAN 550 mg

Indication:
XIFAXAN (rifaximin) 550 mg tablets are indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

XIFAXAN (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults**.**

Important Safety Information about XIFAXAN 550 mg

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.

- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.

- Use with caution in patients with severe (Child-Pugh Class C) hepatic impairment.

- Exercise caution when administrating XIFAXAN concomitantly with a P-glycoprotein (P-gp) inhibitor such as cyclosporine. Concomitant administration of drugs that are P-gp inhibitors can substantially increase the systemic exposure to XIFAXAN. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to XIFAXAN.

- XIFAXAN may cause fetal harm. Discontinue in nursing mothers after taking into account the importance of the drug to the mother.

- The most common adverse reactions for XIFAXAN are peripheral edema, nausea, elevated liver enzymes (ALT), dizziness, fatigue, and ascites.

About Valeant

Valeant Pharmaceuticals International, Inc. (NYSE/TSX:VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, eye health, neurology and branded generics. More information about Valeant can be found at www.valeant.com

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About Salix

Salix Pharmaceuticals, Inc., develops and markets prescription pharmaceutical products and medical devices for the prevention and treatment of gastrointestinal diseases. Salix's strategy is to in-license late-stage or marketed proprietary therapeutic products, complete any required development and regulatory submission of these products, and commercialize them through the Company's specialty sales forces.

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[i] Saito YA, Schoenfeld P, Lock GR 3rd. The epidemiology of irritable bowel syndrome in North America: a systematic review. Am J Gastroenterol. 2002;97:1910-5.

[ii] Lovell RM, Ford AC. Global prevalence of and risk factors for irritable bowel syndrome: a meta analysis. Clin Gastroenterol Hepatol. 2012;10:712-721

[iii] Pimentel, MP et al. Rifaximin Therapy for Patients with Irritable Bowel Syndrome without Constipation. *The New England Journal of Medicine*. 200;364:22-32

To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/salix-announces-fda-approval-of-xifaxan-550-mg-for-the-treatment-of-ibs-d-irritable-bowel-syndrome-with-diarrhea-300089821.html

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