BAUSCH Health

Valeant and Progenics Announce PDUFA Date Extension for Oral RELISTOR

April 04, 2016

-Agency requests standard three-month extension to review additional solicited information-

-New PDUFA date set for July 19, 2016-

LAVAL, Quebec and TARRYTOWN, N.Y., April 4, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) and Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) date for its review of the Oral RELISTOR (methylnaltrexone bromide) new drug application (NDA) by three months to July 19, 2016. The FDA extended the action date to allow for a full review of Valeant's responses to recent information requests from the FDA.

About RELISTOR

Progenics has exclusively licensed development and commercialization rights for its first commercial product, RELISTOR, to Valeant Pharmaceuticals. RELISTOR (methylnaltrexone bromide) Subcutaneous Injection is a treatment for opioid-induced constipation approved in the United States for patients with advanced illness and chronic non-cancer pain.

Important Safety Information about RELISTOR

RELISTOR® (methylnaltrexone bromide) Subcutaneous Injection is contraindicated in patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation.

Cases of gastrointestinal perforation have been reported in adult patients with opioid-induced constipation and advanced illness with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies or peritoneal metastases). Take into account the overall risk-benefit profile when using RELISTOR in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (e.g., Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue RELISTOR in patients who develop this symptom.

If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their physician.

Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, and yawning have occurred in patients treated with RELISTOR. Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal and/or reduced analgesia. Take into account the overall risk-benefit profile when using RELISTOR in such patients. Monitor for adequacy of analgesia and symptoms of opioid withdrawal in such patients.

Avoid concomitant use of RELISTOR with other opioid antagonists because of the potential for additive effects of opioid receptor antagonism and increased risk of opioid withdrawal. RELISTOR may precipitate opioid withdrawal in a fetus and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In nursing mothers, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

In the clinical study in adult patients with opioid-induced constipation and chronic non-cancer pain, the most common adverse reactions (≥ 1%) were abdominal pain, nausea, diarrhea, and hyperhidrosis, hot flush, tremor, and chills.

In clinical studies in adult patients with opioid-induced constipation and advanced illness, the most common adverse reactions (≥ 5%) were abdominal pain, flatulence, nausea, dizziness, and diarrhea.

Please see complete Prescribing Information for RELISTOR. For more information about RELISTOR, please visit
www.relistor.com
.

About the Companies

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, gastrointestinal disorder, eye health, neurology and branded generics. More information about Valeant can be found at
www.valeant.com
.

Progenics Pharmaceuticals, Inc. is developing innovative medicines for oncology, with a pipeline that includes several product candidates in later-stage clinical development. Among the assets in its pipeline of targeted radiotherapy and molecular imaging compounds is AZEDRA™, an ultra-orphan radiotherapy candidate currently in a phase 2 study under an SPA. The Company's PSMA-targeted product candidates for prostate cancer include two small molecule imaging agents 1404 and PyL, and two therapeutic agents PSMA ADC, an antibody drug conjugate, and 1095, a small molecule radiotherapeutic. Progenics' first commercial product, RELISTOR® (methylnaltrexone bromide) for opioid-induced constipation, is partnered with and marketed by Valeant Pharmaceuticals International, Inc.

Additional information on Valeant is available at
http://www.valeant.com

Additional information on Progenics is available at
http://www.progenics.com

Valeant Contacts:
Investor Relations:
Laurie W. Little
(949) 461-6002
laurie.little@valeant.com

Elif McDonald
905-695-7607

elif.mcdonald@valeant.com

Media:
Renée Soto /Jared Levy
Sard Verbinnen & Co.
212-687-8080
rsoto@sardverb.com

Meghan Gavigan
Sard Verbinnen & Co.
415-618-8750
mgavigan@sardverb.com

Progenics Contact:
Melissa Downs, Investor Relations
(914) 789-2801
mdowns@progenics.com

To view the original version on PR Newswire, visit:
http://www.prnewswire.com/news-releases/valeant-and-progenics-announce-pdufa-date-extension-for-oral-relistor-300245266.html

SOURCE Valeant Pharmaceuticals International, Inc.