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Valeant And Progenics Announce FDA Acceptance Of NDA Submission For Oral RELISTOR®

September 08, 2015

LAVAL, Quebec and TARRYTOWN, N.Y., Sept. 8, 2015 /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 accepted for review Valeant's New Drug Application for RELISTOR® (methylnaltrexone bromide) Tablets for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of April 16, 2016.

RELISTOR is a peripherally acting mu-opioid receptor antagonist specifically designed to block the constipating effects of opioid pain medications in the gastrointestinal tract. RELISTOR does not cross the blood-brain barrier, therefore relieving the distressing effects of the constipation without affecting the analgesic effect of the opioid. RELISTOR Subcutaneous Injection has been FDA approved since 2008 to treat OIC in patients with advanced illness who are receiving palliative care, and was approved in 2014 for the treatment of OIC in patients with chronic non-cancer pain.

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
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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
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Progenics Pharmaceuticals, Inc. is developing innovative medicines for oncology, with a pipeline that includes several product candidates in later-stage clinical development. Progenics' first-in-class PSMA-targeted technology platform for prostate cancer includes a small molecule imaging agent that has completed a phase 2 trial and an antibody drug conjugate therapeutic which has also completed a two-cohort phase 2 clinical trial. Among other 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. Progenics' first commercial product, RELISTOR® (methylnaltrexone bromide) for opioid-induced constipation, is partnered with and marketed by Valeant Pharmaceuticals International, Inc. For additional information, please visit
www.progenics.com
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Editor's Note:

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

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To view the original version on PR Newswire, visit:
http://www.prnewswire.com/news-releases/valeant-and-progenics-announce-fda-acceptance-of-nda-submission-for-oral-relistor-300138864.html
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