BAUSCH Health

RELISTOR® Receives Positive CHMP Opinion in the EU for the Treatment of Opioid-Induced Constipation in Adults with Chronic Non-Cancer Pain

April 24, 2015

LAVAL, Quebec and TARRYTOWN, N.Y., April 24, 2015 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) and Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending a new indication for RELISTOR® (methylnaltrexone bromide) Subcutaneous Injection for the treatment of opioid-induced constipation (OIC) when response to laxative therapy has not been sufficient in adult patients, aged 18 years and older. Additionally, the Committee has recommended a one-year extension of data/marketing protection for RELISTOR, to 11 years from the date of approval, citing the fact that RELISTOR offers a major contribution to patient care in comparison to existing therapies.

The CHMP is responsible for reviewing medicinal product applications for safety, quality and efficacy. The CHMP's positive opinion on RELISTOR will be reviewed by the European Commission, which has the authority to approve medicines for the European Union. The final decision will be applicable to all 28 European Union member countries plus Iceland and Norway. If approved, it is anticipated that RELISTOR will be immediately available to this newly expanded population of patients in the EU using opioids to control chronic non-cancer pain.

"The positive CHMP opinion brings RELISTOR one step closer to providing a treatment for the millions of patients in Europe who suffer from debilitating constipation while taking opioids for chronic non-cancer pain," said Mark Baker , Chief Executive Officer of Progenics. "RELISTOR offers a meaningful benefit to patients who are unable to manage their constipation with less effective laxative therapies."

Tage Ramakrishna , M.D., Chief Medical Officer of Valeant, added, "Today's positive opinion recognizes the clinical benefit of RELISTOR, which treats the underlying cause of OIC without interfering with the centrally acting analgesic properties of the opioid. We are committed to realizing the full potential of this important franchise, and if approved, we will work quickly to bring this needed medicine to European patients."

About RELISTOR

Progenics has exclusively licensed development and commercialization rights for its first commercial product, RELISTOR, to Salix Pharmaceuticals, Ltd., a Valeant Pharmaceuticals International, Inc. company. RELISTOR (methylnaltrexone bromide) Subcutaneous Injection is a first-in-class treatment for opioid-induced constipation approved in the United States for patients with chronic non-cancer pain, and in the U.S. and more than 50 other countries for patients with advanced illness.

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 ($\geq$ 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 ($\geq$ 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, eye health, neurology and

branded generics. More information about Valeant Pharmaceuticals International, inc. 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 an antibody drug conjugate therapeutic which completed a two-cohort phase 2 clinical trial and a small molecule imaging agent that has also completed a phase 2 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 Salix Pharmaceuticals, Ltd., a Valeant Pharmaceuticals International, Inc. company. For additional information, please visit
www.progenics.com
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Additional information concerning Progenics and its business may be available in press releases or other public announcements and public filings made after this release. For more information, please visit
www.progenics.com
. Please follow us on LinkedIn®.

Information on or accessed through our website or social media sites is not included in the company's SEC filings.

Forward-looking Statements
This press release may contain forward-looking statements, including, but not limited to, statements regarding the positive opinion from CHMP, the recognition of the clinical benefit of RELISTOR, the approval of RELISTOR, and the potential to bring this product to European patients. Forward-looking statements may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management of Valeant and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include the risks and uncertainties discussed in Valeant's most recent annual or quarterly report and detailed from time to time in Valeant's other filings with the Securities and Exchange Commission (the "SEC") and the Canadian Securities Administrators, which factors are incorporated herein by

reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Valeant undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this press release or to reflect actual outcomes.

Editor's Note:

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