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Valeant And Progenics Announce The U.S. Commercial Launch Of FDA-Approved Relistor® Tablets

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LAVAL, Quebec, Sept. 6, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) ("Valeant") and Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) ("Progenics") today announced the U.S. commercial launch of RELISTOR® (methylnaltrexone bromide) Tablets, which is now available for prescribing. RELISTOR Tablets (450 mg once daily) were approved by the U.S. Food and Drug Administration (FDA) for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain on July 19, 2016.

"We are very pleased to launch RELISTOR Tablets in the U.S. and provide an exceptional new treatment option for the millions of patients who suffer from extreme discomfort due to OIC," said Joseph C. Papa, Chief Executive Officer of Valeant. "This new method of delivery for RELISTOR offers healthcare professionals a novel alternative to address the treatment of OIC – a growing need in pain management – and demonstrates Valeant's continued commitment to delivering innovative products that improve people's lives."

In addition, RELISTOR Tablets will be highlighted during poster presentations at PAINWeek, the largest U.S. pain conference for frontline clinicians, in Las Vegas, Nevada, from September 6-10. The posters will include the following:

- Webster LR, Harper JR, Israel RJ. "Oral methylnaltrexone is efficacious and well tolerated for the treatment of opioid-induced constipation in patients with chronic noncancer pain taking concomitant methadone." PAINWeek Poster, public viewing begins on Thursday, September 8 at 12:30 p.m. PT.
- Webster LR, Harper JR, Israel RJ. "Oral methylnaltrexone does not negatively impact analgesia in patients with opioid-induced constipation and chronic noncancer pain." PAINWeek Poster, public viewing begins on Thursday, September 8 at 12:30 p.m. PT.

The RELISTOR Tablets data will also be presented by Steven Simon, M.D., Professor of Pathology, University of Miami Health System, during a product theatre, "Opioid-Induced Constipation When Reliable and Rapid Relief Matters," on Friday, September 9 at 8 a.m. PT.

Important Safety Information about RELISTOR

RELISTOR® (methylnaltrexone bromide) Tablets are 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 OIC 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 healthcare provider.

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.

The most common adverse reactions (≥ 12%) in adult patients with opioid-induced constipation and chronic non-cancer pain receiving RELISTOR tablets were abdominal pain, diarrhea, headaches, abdominal distention, hyperhidrosis, anxiety, muscle spasms, rhinorrhea, and chills. Adverse reactions of abdominal pain, diarrhea, hyperhidrosis, anxiety, rhinorrhea, and chills may reflect symptoms of opioid withdrawal.

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

About RELISTOR

Progenics has exclusively licensed development and commercialization rights for its first commercial product, RELISTOR, to Valeant. RELISTOR Tablets (450 mg once daily) is approved in the United States for the treatment of OIC in patients with chronic non-cancer pain. RELISTOR Subcutaneous Injection (12 mg and 8 mg) is a treatment for opioid-induced constipation approved in the United States and worldwide for patients with advanced illness and chronic non-cancer pain.

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

Progenics Pharmaceuticals, Inc. is developing innovative medicines and other products for targeting and treating cancer, with a pipeline that includes several product candidates in later-stage clinical development. These products in development include therapeutic agents designed to precisely target cancer (AZEDRA® and 1095), and PSMA-targeted imaging agents for prostate cancer (1404 and PyL™) intended to enable clinicians and patients to accurately visualize and manage their disease. Progenics recently entered into an agreement with a subsidiary of Bayer AG granting Bayer exclusive worldwide rights to develop and commercialize products using our PSMA antibody technology in combination with alpha-emitting radionuclides. In addition, in late 2015 Progenics acquired EXINI Diagnostics AB, a leader in the development of advanced artificial intelligence-based imaging analysis tools and solutions for medical decision support. The

acquisition of EXINI complements Progenics' strategy to support its imaging and therapeutic agents with sophisticated analytical tools and other technologies to help physicians and patients visualize, understand, target and treat cancer. Progenics' first commercial product, RELISTOR® (methylnaltrexone bromide) for opioid-induced constipation, is partnered with and marketed by Valeant Pharmaceuticals International, Inc. Additional information on Progenics is available at
http://www.progenics.com
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Forward-looking Statements
This press release contains forward-looking statements. 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 and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. 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. Neither Valeant nor Progenics undertakes any 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, unless required by law. *Additional information concerning Valeant and Progenics and such risks and uncertainties is available on their respective websites, and in the press releases and reports filed with the U.S. Securities and Exchange Commission and, in the case of Valeant, with the Canadian Securities Administrators.*

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