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Valeant and Progenics Announce FDA Approves RELISTOR® Tablets for the Treatment of Opioid-Induced Constipation in Adults with Chronic Non-cancer Pain

July 19, 2016

LAVAL, Quebec and TARRYTOWN, N.Y., July 19, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE & TSX: VRX) and Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced that the U.S. Food and Drug Administration has approved RELISTOR® (methylnaltrexone bromide) Tablets for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain. Valeant expects to commence sales of RELISTOR Tablets in the U.S. in the third quarter of 2016.

"Opioid-induced constipation represents a long-lasting and potentially debilitating side effect of opioid therapy for millions of patients suffering from chronic pain," commented Joseph C. Papa, Chief Executive Officer of Valeant. "We believe Oral RELISTOR represents a new alternative treatment for OIC, and we look forward to introducing the more convenient oral formulation as soon as practicable."

"We are delighted that this milestone for RELISTOR has been achieved, and that patients suffering from OIC will have this new treatment option," said Mark Baker, Chief Executive Officer of Progenics. "We expect the market to be receptive to a more convenient oral tablet formulation of RELISTOR's well-established subcutaneous preparation. We would like to thank, in particular, Dr. Tage Ramakrishna and Dr. Robert Israel of Valeant for their work over many years in the clinical development of RELISTOR."

"RELISTOR has a unique mechanism of action that binds to mu-opioid receptors without impacting the opioid-mediated analgesic effects on the central nervous system," said Richard L. Rauck, MD, Medical Director, Center for Clinical Research, President, Carolinas Pain Institute, President of the Sceptor Pain Foundation of which he is a founding member, and Immediate Past President of the World Institute of Pain. "This represents a true breakthrough in the treatment of OIC, and addresses a large and growing need in the field of pain management."

Today, the FDA approved RELISTOR Tablets (450 mg once daily) for the treatment of OIC in adults with chronic non-cancer pain. Previously, RELISTOR Subcutaneous Injection (12 mg and 8 mg) was approved in 2008 for the treatment of OIC in adults with advanced illness who are receiving palliative care and in 2014 for the treatment of OIC in adults with chronic non-cancer pain.

About the Phase 3 Clinical Trial of Oral RELISTOR for OIC in Chronic Non-Cancer Pain (NCP)

A randomized, double-blind, Phase 3 trial was conducted to evaluate once-daily dosing of 450 mg (n=200) methylnaltrexone (MNTX) tablets compared to placebo (n=201) in adults with chronic NCP. In the 450 mg treatment arm, MNTX tablets demonstrated statistically significant improvements in rescue-free bowel movement (RFBM) within 4 hours of administration over 28

days of dosing when compared to placebo treatment, achieving the primary endpoint. The 450 mg treatment group also achieved statistical significance for the first key secondary efficacy endpoint where a higher percentage of responders (i.e., had ≥3 RFBMs/week, with an increase of ≥1 RFBM/week from baseline for at least 3 of the 4 weeks) was observed with MNTX treatment as compared to placebo. Overall, efficacy of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic, non-cancer pain. The overall observed safety profile seen in patients treated with oral methylnaltrexone was comparable to placebo in this study.

Important Safety Information about RELISTOR

RELISTOR® (methylnaltrexone bromide) Tablets 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 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 valeant.com. For more information about RELISTOR, please visit
www.relistor.com
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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
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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 may contain projections and other "forward-looking statements" regarding future events, including, but not limited to statements respecting the anticipated timing of the commenced of sales of Oral RELISTOR, the expected market reaction to Oral RELISTOR and statements referring to Progenics' or Valeant's estimated or anticipated future results or other non-historical facts. Forward-looking statements reflect and our based on Progenics' and Valeant's respective current beliefs, expectations and perspectives on existing trends and information as of the date of this communication. Forward looking statements generally will be accompanied by words such as "anticipate," "believe," "plan," "could," "should," "would," "estimate," "expect," "forecast," "outlook," "guidance," "intend," "may," "might," "will," "possible," "potential," "predict," "project," "target," "continue" or other similar words, phrases or expressions. Such statements are predictions only, and are subject to certain risks and uncertainties that could cause actual events or results to differ materiallyfrom those described in the forward-looking statements. These risks and uncertainties include the risk and uncertainties described on Progenics' and Valeant's respective websites, and in their respective press releases and reports filed with the U.S. Securities and Exchange Commission and, in the case of Valeant, the Canadian Securities Administrators, which risks and uncertainties are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. Progenics and Valeant are providing the information in this press release as of its date and, except as expressly required by law, Progenics and Valeant each disclaim any intent or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or circumstances or otherwise.

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