



Summary Judgment Granted Upholding the Validity of Formulation Patent Protecting RELISTOR® Injection

May 3, 2018

RELISTOR® Injection Protected from Generic Competition Until 2024

NEW YORK, May 02, 2018 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX) reported that its partner Valeant Pharmaceuticals International, Inc. today announced that the U.S. District Court for the District of New Jersey has granted a motion for partial summary judgment of validity of a formulation patent for RELISTOR® (methylnaltrexone bromide) Injection. The ruling prevents generic competition in the United States until 2024.

Plaintiffs in the case, including Progenics, Salix Pharmaceuticals, Inc., Valeant and Wyeth LLC, had filed a motion for summary judgment on challenges to the validity of Claim 8 of U.S. Patent No. 8,552,025, which protects the formulation of RELISTOR® Injection.

Defendants in the case, which include Mylan Inc., Mylan Laboratories LTD., Mylan Pharmaceuticals, Inc. and Actavis LLC., had previously stipulated to infringement of Claim 8 and have no remaining invalidity defenses.

In the upcoming trial on June 4, the court is expected to decide the infringement and validity of other patents that could prevent generic RELISTOR® vials until 2029 and generic RELISTOR® syringes until 2030.

About RELISTOR®

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

IMPORTANT SAFETY INFORMATION - RELISTOR (methylnaltrexone bromide) tablets, for oral use and RELISTOR (methylnaltrexone bromide) injection, for subcutaneous use

RELISTOR tablets and injection 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 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 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 and should be monitored for adequacy of analgesia and symptoms of opioid withdrawal.

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 use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the immature fetal blood brain barrier and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because of the potential for serious adverse reactions, including opioid withdrawal, in breastfed infants, advise women that breastfeeding is not recommended during treatment with RELISTOR. 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.

A dosage reduction of RELISTOR tablets and RELISTOR injection is recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute as estimated by Cockcroft-Gault). No dosage adjustment of RELISTOR tablets or RELISTOR injection is needed in patients with mild renal impairment.

A dosage reduction of RELISTOR tablets is recommended in patients with moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. No dosage adjustment of RELISTOR tablets is needed in patients with mild hepatic impairment (Child-Pugh Class A). No dosage adjustment of RELISTOR injection is needed for patients with mild or moderate hepatic impairment. In patients with severe hepatic impairment, monitor for methylnaltrexone-related adverse reactions.

In the clinical studies, the most common adverse reactions were:

OIC in adult patients with chronic non-cancer pain

- RELISTOR tablets ($\geq 2\%$ of RELISTOR patients and at a greater incidence than placebo): abdominal pain (14%), diarrhea

(5%), headache (4%), abdominal distention (4%), vomiting (3%), hyperhidrosis (3%), anxiety (2%), muscle spasms (2%), rhinorrhea (2%), and chills (2%).

- RELISTOR injection ($\geq 1\%$ of RELISTOR patients and at a greater incidence than placebo): abdominal pain (21%), nausea (9%), diarrhea (6%), hyperhidrosis (6%), hot flush (3%), tremor (1%), and chills (1%).

OIC in adult patients with advanced illness

- RELISTOR injection ($\geq 5\%$ of RELISTOR patients and at a greater incidence than placebo): abdominal pain (29%) flatulence (13%), nausea (12%), dizziness (7%), and diarrhea (6%).

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

About Progenics

Progenics develops innovative medicines and other technologies to target and treat cancer. Progenics' pipeline includes: 1) therapeutic agents designed to precisely target cancer (AZEDRA[®], 1095, and PSMA TTC), 2) PSMA-targeted imaging agents for prostate cancer (1404 and PyL[™]), and 3) imaging analysis technology. Progenics' first commercial product, RELISTOR[®] (methylnaltrexone bromide) for opioid-induced constipation, is partnered with Valeant Pharmaceuticals International, Inc.

This press release contains projections and other "forward-looking statements" regarding future events. Statements contained in this communication that refer to Progenics' estimated or anticipated future results or other non-historical facts are forward-looking statements that reflect Progenics' current perspective of 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," "estimate," "expect," "forecast," "outlook," "guidance," "intend," "may," "might," "will," "possible," "potential," "predict," "project," or other similar words, phrases or expressions. Such statements are predictions only, and are subject to risks and uncertainties that could cause actual events or results to differ materially. These risks and uncertainties include, among others, the cost, timing and unpredictability of results of clinical trials and other development activities and collaborations; the unpredictability of the duration and results of regulatory review of New Drug Applications (NDA) and Investigational NDAs, including our NDA for AZEDRA; market acceptance for approved products; possible product safety or efficacy concerns, general business, financial, regulatory and accounting matters, litigation and other risks. More information concerning Progenics and such risks and uncertainties is available on its website, and in its press releases and reports it files with the U.S. Securities and Exchange Commission, including those risk factors included in its Annual Report on Form 10-K for the annual period ended December 31, 2017. Progenics is providing the information in this press release as of its date and, except as expressly required by law, Progenics disclaims 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.

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

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