



## **Progenics Pharmaceuticals and Salix Pharmaceuticals Announce Worldwide License Agreement for RELISTOR®**

**— RELISTOR Currently Marketed as First-in-Class Treatment for Opioid-Induced Constipation in Advanced Illness Patients —**

**— Supplemental NDA Submission Planned in 2011 to Potentially Expand Market to Chronic, Non-Malignant Pain —**

**— Phase 3 Trial of Oral RELISTOR in Chronic, Non-Malignant Pain Expected to Complete Enrollment by Year-End 2011**

TARRYTOWN, N.Y. & RALEIGH, N.C.--(BUSINESS WIRE)-- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX) and Salix Pharmaceuticals, Ltd. (Nasdaq:SLXP) today announced that they have entered into an exclusive worldwide (except Japan) agreement by which Salix has licensed rights to RELISTOR® (methylnaltrexone bromide). RELISTOR Subcutaneous Injection is indicated for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Use of RELISTOR beyond 4 months has not been studied.

RELISTOR is a peripherally acting mu-opioid receptor antagonist that counteracts the constipating effects of opioid pain medications in the gastrointestinal tract without affecting their ability to relieve pain. The methylnaltrexone license includes intellectual property from the University of Chicago, Progenics Pharmaceuticals, and Wyeth Pharmaceuticals, including patents and applications with expiration dates that will range from 2017 through 2031. RELISTOR was approved in the United States in 2008, and currently the drug is approved for use in over 50 countries worldwide. In 2010, RELISTOR single-use, pre-filled syringes were approved for use in the United States, Canada and the European Union. Worldwide net sales of RELISTOR totaled \$16 million in 2010.

Financial terms of the transaction include a \$60 million up-front payment and development milestones totaling \$90 million, contingent upon the achievement of certain U.S. regulatory milestones. Salix also will pay sales-based milestones of up to \$200 million plus royalties on product sales in the U.S., as well as 60% of all revenue received from non-U.S. sublicensees. Salix will fund all development, registration and commercialization activities for RELISTOR in markets worldwide other than in Japan, where Progenics has licensed to Ono Pharmaceuticals the rights to develop and commercialize subcutaneous RELISTOR.

Commenting on the transaction, Mark R. Baker, President, Progenics, stated, "Our agreement with Salix represents the culmination of our search for a partner with the skills, experience and passion to effectively market and develop RELISTOR. With the strength of Salix's sales force and development team behind this product, I believe that RELISTOR's full potential can be achieved -- to the benefit of OIC patients."

"Paul J. Maddon, M.D., Ph.D., Founder, Chief Executive and Chief Science Officer, Progenics, stated, "Our partnership with Salix maximizes the global development, commercialization and market potential of the RELISTOR franchise. Progenics and Salix share a vision of expanding the use of this important therapy among the millions of patients who suffer from the debilitating side effects of opioid pain medications."

Carolyn Logan, President and CEO, Salix, stated, "Constipation is a common, and often debilitating, gastrointestinal consequence of the use of opioid analgesics to manage pain. We are pleased to add RELISTOR Subcutaneous Injection, a first-in-class treatment for OIC in advanced illness, to our product portfolio. We believe RELISTOR represents a valuable asset that merits additional development and targeted commercialization. Currently an oral formulation of RELISTOR is in phase 3 development to potentially address OIC in patients with chronic, non-cancer pain. We look forward to utilizing our specialty sales force in the United States and our existing business partners worldwide to provide physicians with a solution to address the opioid-induced constipation experienced by their patients."

Salix will market RELISTOR directly through its specialty sales force in the U.S., and outside the U.S., RELISTOR will be marketed with sublicenses to regional companies. The parties plan an April 2011 transition of RELISTOR commercial and development responsibility to Salix from Pfizer Inc, which acquired Progenics' former RELISTOR partner, Wyeth Pharmaceuticals. While Salix effects a country-by-country transition of ex-U.S. commercialization rights, Wyeth will remain the Marketing Authorization Holder for RELISTOR and will continue to supply product. In the interim, Wyeth remains responsible for all manufacturing, clinical, medical and regulatory activities for RELISTOR outside of the U.S. and Japan.

**Conference Calls and Audiocasts**

Members of Progenics' senior management team will host a conference call today at 8:00 a.m. ET.

To participate in the conference call, please dial 800-419-9895 (domestic) or 913-312-9308 (international) and reference the access code 7236120. A replay of the call will be available from 11:00 a.m. ET on Monday, February 7, 2011 until midnight on Sunday, February 20, 2011. To access the replay, please dial 888-203-1112 (domestic) or 719-457-0820 (international) and reference the access code 7236120. The archived webcast will be available for 14 days in the Events section of the Progenics website at <http://www.progenics.com/events.cfm>.

Members of Salix's senior management team will host a conference call today at 9:00 a.m. ET.

To participate in the conference call, please dial 866-454-4205 (domestic) or 913-312-0662 (international) and reference the access code 8513768. A replay of the call will be available from 11:30 a.m. ET on Monday, February 7, 2011 until midnight on Sunday, February 20, 2011. To access the replay, please dial 888-203-1112 (domestic) or 719-457-0820 (international) and reference the access code 8513768.

### **About Opioids, Constipation and RELISTOR (methylnaltrexone bromide)**

Opioid analgesics are frequently prescribed to manage pain in patients with advanced illness. Constipation commonly occurs in palliative-care patients receiving opioid therapy for pain. RELISTOR is the first approved medication that specifically targets the underlying cause of OIC in these patients. Opioids relieve pain by specifically interacting with mu-opioid receptors within the brain and spinal cord of the central nervous system (CNS). However, opioids also interact with mu-opioid receptors found outside the CNS, such as those within the gastrointestinal tract, resulting in constipation that can be debilitating. RELISTOR is a peripherally acting mu-opioid receptor antagonist that decreases the constipating effects of opioid pain medications without affecting their ability to relieve pain. RELISTOR selectively displaces opioids from the mu-opioid receptors outside the CNS, including those located in the gastrointestinal tract, thereby decreasing their constipating effects. Because of its chemical structure, RELISTOR does not affect the opioid-mediated analgesic effects on the CNS.

RELISTOR Subcutaneous Injection is approved in the United States for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. The use of RELISTOR beyond four months has not been studied. The drug is also approved for use in over 50 countries worldwide, including the European Union, Canada, and Australia. In the 27 member states of the E.U., as well as Iceland, Norway and Liechtenstein, RELISTOR is approved for the treatment of opioid-induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. In Canada, the drug is approved for the treatment of opioid-induced constipation in patients with advanced illness, receiving palliative care. When response to laxatives has been insufficient, RELISTOR should be used as an adjunct therapy to induce a prompt bowel movement. Applications in additional countries are pending.

### **Important Safety Information for RELISTOR**

- RELISTOR is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction
- If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their physician
- Rare cases of gastrointestinal (GI) perforation have been reported in advanced illness patients. Use RELISTOR with caution in patients with known or suspected lesions of the GI tract
- Use of RELISTOR has not been studied in patients with peritoneal catheters
- The most common adverse reactions reported with RELISTOR compared with placebo in clinical trials were abdominal pain (28.5% vs. 9.8%), flatulence (13.3% vs. 5.7%), nausea (11.5% vs. 4.9%), dizziness (7.3% vs. 2.4%), diarrhea (5.5% vs. 2.4%), and hyperhidrosis (6.7% vs. 6.5%)
- Safety and efficacy of RELISTOR have not been established in pediatric patients

RELISTOR full Prescribing Information for the U.S. is available at [www.relistor.com](http://www.relistor.com).

### **RELISTOR Development Programs**

#### **Subcutaneous Methylnaltrexone in chronic, non-malignant pain and OIC**

A 1,034-patient, one-year, open-label, international, phase 3 safety study to evaluate the long-term safety and tolerability of methylnaltrexone bromide subcutaneous injection in chronic, non-malignant pain patients with opioid-induced constipation was completed in September 2010. Efforts are underway to submit a supplemental New Drug Application for this potential indication to the FDA in the first half of 2011.

## Oral Methylnaltrexone in chronic, non-malignant pain and OIC

A 700-patient, international, randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of oral methylnaltrexone to treat opioid-induced constipation in chronic, non-malignant pain patients was initiated in September 2010, and is anticipated to complete enrollment by year-end 2011.

### About Progenics

Progenics Pharmaceuticals, Inc., of Tarrytown, NY, is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Principal programs are directed toward gastroenterology, oncology and infectious diseases.

Progenics is developing RELISTOR<sup>®</sup> (methylnaltrexone bromide) for the treatment of opioid-induced constipation. RELISTOR is now approved in over 50 countries, including the U.S., E.U., Canada and Australia. Ono Pharmaceutical Co., Ltd. has an exclusive license from Progenics for development and commercialization of subcutaneous RELISTOR in Japan. In oncology, the Company is conducting a phase 1 clinical trial of PSMA ADC, a human monoclonal antibody-drug conjugate for the treatment of prostate cancer. PSMA is a protein found on the surface of prostate cancer cells as well as in blood vessels supplying other solid tumors. In virology, Progenics is also developing the viral-entry inhibitor PRO 140, a humanized monoclonal antibody which binds to co-receptor CCR5 to inhibit human immunodeficiency virus (HIV) infection. PRO 140 is currently in phase 2 clinical testing. In early development, Progenics is evaluating novel antibodies to toxins produced by the bacteria *C. difficile*, as well as single-agent multiplex PI3-Kinase inhibitors as a potential strategy to combat some of the most aggressive forms of cancer, and is also seeking to identify novel entry-inhibitors of HCV infection.

For more information, please visit [www.progenics.com](http://www.progenics.com).

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### About Salix

Salix Pharmaceuticals, Ltd., headquartered in Raleigh, North Carolina, develops and markets prescription pharmaceutical products for the prevention and treatment of gastrointestinal diseases. Salix's strategy is to in-license late-stage or marketed proprietary therapeutic drugs, complete any required development and regulatory submission of these products, and market them through the Company's gastroenterology specialty sales and marketing team.

Salix trades on the NASDAQ Global Select Market under the ticker symbol "SLXP".

For more information, please visit the Salix Website at [www.salix.com](http://www.salix.com) or contact Salix at 919-862-1000. Follow Salix on Twitter (@SalixPharma) and Facebook ([www.facebook.com/SalixPharma](http://www.facebook.com/SalixPharma)). Information on the Salix web site, Twitter and Facebook is not incorporated in the Company's SEC filings.

*Please Note: The materials provided herein contain projections and other forward-looking statements regarding future events. Such statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: the unpredictability of the duration and results of regulatory review of New Drug Applications and Investigational NDAs; market acceptance for approved products; the cost, timing and results of clinical trials and other development activities involving pharmaceutical products; generic and other competition; litigation and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties; and revenue recognition and other critical accounting policies. More information concerning the Companies is available on their websites, as well as in press releases and reports they file with the U.S. Securities and Exchange Commission.*

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