



## **Progenics Pharmaceuticals Announces Phase 2 Clinical Trial of Subcutaneous Methylalntrexone in Japan by Ono Pharmaceutical**

TARRYTOWN, N.Y.--(BUSINESS WIRE)-- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced the initiation of a phase 2 clinical trial of subcutaneous methylalntrexone in Japan by its collaborator, Ono Pharmaceutical Co., Ltd. (OSE-TYO: 4528). The drug, designated ONO-3849 in Japan, is being evaluated for the treatment of opioid-induced constipation (OIC) in patients with advanced illness such as cancer. Subcutaneous methylalntrexone is already marketed in the U.S. and in certain ex-U.S. markets under the brand name RELISTOR®.

"Ono's commencement of this trial is an important step for the expansion of the methylalntrexone franchise into Japan," said Paul J. Maddon, M.D., Ph.D., Progenics' Founder, Chief Executive and Chief Science Officer. "Their work complements ours in the U.S., where we are planning to submit a supplemental New Drug Application for subcutaneous RELISTOR in chronic, non-cancer pain patients, and recently have initiated a phase 3 study of oral RELISTOR."

Ono's phase 2, multi-center, randomized, double-blind, placebo-controlled, parallel-group comparison study is designed to demonstrate efficacy and safety of subcutaneous methylalntrexone in Japanese subjects.

### **About RELISTOR**

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 in the European Union, Canada, Australia and Brazil. Applications in additional countries are pending. 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. RELISTOR is the brand name under which methylalntrexone is marketed outside Japan by Wyeth, a wholly-owned subsidiary of Pfizer.

### **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 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.**

### **About the Progenics-Ono Collaboration**

Ono Pharmaceutical has an exclusive license from Progenics to the subcutaneous form of methylalntrexone (RELISTOR), designated ONO-3849 in Japan, where it is developing and plans to commercialize the drug for the treatment of opioid-induced constipation. Under their agreement, Ono is responsible for conducting the clinical development necessary to support

regulatory marketing approval. Progenics received an upfront fee for the license and is entitled to commercial and development milestones, as well as royalties on sales of methylalntrexone in Japan.

(PGNX-C)

## 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> (methylalntrexone bromide) for the treatment of opioid-induced constipation. RELISTOR is now approved in over 50 countries, including the U.S., E.U., Canada, Australia and Brazil. Progenics is pursuing strategic options for RELISTOR, including licensing, collaboration, strategic alliances and U.S. commercialization or co-promotion, following termination of its 2005 collaboration with Wyeth Pharmaceuticals, now a Pfizer Inc. subsidiary, which is continuing manufacturing, sales, marketing, clinical, and certain development and regulatory activities for RELISTOR during the transition. 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. Progenics also is developing the viral-entry inhibitor PRO 140, a humanized monoclonal antibody to inhibit human immunodeficiency virus (HIV) infection, which is currently in phase 2 clinical testing. In early development, Progenics is evaluating novel antibodies to toxins produced by the bacterium *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.

**DISCLOSURE NOTICE:** *This document contains statements that do not relate strictly to historical fact, any of which may be forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. When we use the words "anticipates," "plans," "expects" and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. While it is impossible to identify or predict all such matters, these differences may result from, among other things, the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products appearing promising in early trials will not demonstrate efficacy or safety in larger-scale trials; clinical trial data on our products and product candidates will be unfavorable; our products will not receive marketing approval from regulators or, if approved, do not gain sufficient market acceptance to justify development and commercialization costs; competing products currently on the market or in development might reduce the commercial potential of our products; we, our collaborators or others might identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not originating from subsequent testing or other activities by us, governmental regulators, other entities or organizations or otherwise, and whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, declining sales or other adverse events.*

*We are also subject to risks and uncertainties associated with the actions of our corporate, academic and other collaborators and government regulatory agencies, including risks from market forces and trends; potential product liability; intellectual property, litigation, environmental and other risks; the risk that we may not be able to enter into favorable collaboration or other relationships or that existing or future relationships may not proceed as planned; the risk that current and pending patent protection for our products may be invalid, unenforceable or challenged, or fail to provide adequate market exclusivity, or that our rights to in-licensed intellectual property may be terminated for our failure to satisfy performance milestones; the risk of difficulties in, and regulatory compliance relating to, manufacturing products; and the uncertainty of our future profitability.*

*Risks and uncertainties also include general economic conditions, including interest and currency exchange-rate fluctuations and the availability of capital; changes in generally accepted accounting principles; the impact of legislation and regulatory compliance; the highly regulated nature of our business, including government cost-containment initiatives and restrictions on third-party payments for our products; trade buying patterns; the competitive climate of our industry; and other factors set forth in our Annual Report on Form 10-K and other reports filed with the U.S. Securities and Exchange Commission. In particular, we cannot assure you that RELISTOR will be commercially successful or be approved in the future in other formulations, indications or jurisdictions, or that any of our other programs will result in a commercial product.*

*We do not have a policy of updating or revising forward-looking statements and we assume no obligation to update any statements as a result of new information or future events or developments. It should not be assumed that our silence over time means that actual events are bearing out as expressed or implied in forward-looking statements.*

Editors Note:

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

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

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Source: Progenics Pharmaceuticals, Inc.

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