



Progenics Announces Initiation of RELISTOR Clinical Trials in Japan by Ono Pharmaceutical

- Japanese pharmaceutical company begins clinical development of first-in-class opioid-induced constipation medication -

TARRYTOWN, N.Y., Jun 08, 2009 (BUSINESS WIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced that its collaborator, Ono Pharmaceutical Co., Ltd., Osaka, Japan (OSE-TYO: 4528) has begun clinical testing in Japan of RELISTOR^(R) (methylnaltrexone bromide) subcutaneous injection, the first-in-class medicine approved in the U.S., Canada, the European Union, Australia and Latin American countries for the treatment of opioid-induced constipation. Ono has exclusive rights to subcutaneous RELISTOR in Japan, where it is pursuing plans to develop and commercialize the drug, designated ONO-3849, for the treatment of opioid-induced constipation. RELISTOR is being developed and commercialized in the rest of the world by Progenics and Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE).

ONO-3849 is being developed in Japan according to the regulatory agency guidelines of Japan's Ministry of Health, Labor and Welfare, and will be evaluated in Japanese patients with opioid-induced constipation.

"Our collaboration with Ono exemplifies Progenics' corporate strategy of maximizing market access to RELISTOR through key geographic development and commercialization partnerships," said Paul J. Maddon, M.D., Ph.D., Progenics' Founder, Chief Executive Officer and Chief Science Officer. "We believe the advancement of RELISTOR into clinical studies in Japan demonstrates a shared commitment of both organizations to providing patients in Japan who suffer from opioid-induced constipation access to this first-in-class product, if approved."

In October of last year, Progenics announced an agreement by which Ono has rights in Japan to the subcutaneous form of RELISTOR, and is responsible for developing and commercializing subcutaneous RELISTOR in Japan, including conducting the clinical development necessary to support regulatory marketing approval. Under the agreement, Progenics received an upfront fee, and is entitled to commercial and development milestones, as well as royalties on sales of RELISTOR in Japan.

About Subcutaneous RELISTOR

RELISTOR, administered via subcutaneous injection, is a peripherally acting mu-opioid receptor antagonist that decreases the constipating effects of opioid pain medications in the gastrointestinal tract without affecting their ability to relieve pain.

In April of 2008, the U.S. Food and Drug Administration approved RELISTOR subcutaneous injection 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. The use of RELISTOR beyond four months has not been studied. RELISTOR is now approved in over 30 countries, including the U.S., Canada, the European Union, Latin American countries and Australia. Other applications in additional countries are also pending.

Important Safety Information for Subcutaneous 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.
- Use of RELISTOR has not been studied in patients with peritoneal catheters.
- The most common adverse reactions reported with RELISTOR in U.S. clinical trials were abdominal pain, flatulence, and nausea.
- Full RELISTOR Prescribing Information for the U.S. is available at www.relistor.com.

About the Progenics-Wyeth Worldwide Collaboration

Commercial sales of subcutaneous RELISTOR under the Progenics-Wyeth collaboration began last year in the United States, Canada and Europe following regulatory approvals in each of these regions. RELISTOR is currently approved for use in over 30 countries.

About the Company

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, virology--including human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infections--and oncology. Progenics, in collaboration with Wyeth, is developing RELISTOR^(R) (methylnaltrexone bromide) for the treatment of opioid-induced side effects. RELISTOR is currently approved in over 30 countries, which include approvals in the U.S., Canada and Australia, Latin American countries, as well as all European Union member countries. In the U.S., 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. Marketing applications are pending for RELISTOR in other countries. In the area of virology, Progenics is developing the HIV-entry inhibitor PRO 140, a humanized monoclonal antibody which binds to co-receptor CCR5 to inhibit HIV entry. PRO 140 is currently in phase 2 clinical testing for the treatment of HIV infection. The Company also has an HCV discovery program to identify novel inhibitors of viral entry. In the area of oncology, the Company is conducting a phase 1 clinical trial of a human monoclonal antibody-drug conjugate (ADC) for the treatment of prostate cancer--a selectively targeted chemotherapeutic antibody directed against prostate-specific membrane antigen (PSMA). PSMA is a protein found on the surface of prostate cancer cells as well as in blood vessels supplying other solid tumors. Progenics is also conducting a phase 1 clinical trial with a vaccine designed to treat prostate cancer by stimulating an immune response to PSMA.

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; 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, such as those relating to the recently-announced acquisition of our RELISTOR collaborator, Wyeth Pharmaceuticals, by Pfizer Inc.; potential product liability; intellectual property, litigation, environmental and other risks; the risk that licenses to 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 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 about Progenics Pharmaceuticals, Inc., please visit www.progenics.com.

For more information about RELISTOR, please visit www.RELISTOR.com.

Additional information on Ono is available at <http://www.ono.co.jp/eng/default.htm>.

SOURCE: Progenics Pharmaceuticals, Inc.

Investors:

Progenics Pharmaceuticals, Inc.
Richard W. Krawiec, Ph.D., 914-789-2814
Vice President, Corporate Affairs
rkrawiec@progenics.com

or

Dory A. Lombardo, 914-789-2818
Associate Director, Corporate Affairs
dlombardo@progenics.com

or

Media:

WeissComm Partners
Aline Schimmel, 312-646-6295

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