



Progenics Initiates Phase 2 Clinical Trials for PRO 140, a Novel HIV Antibody Therapy

TARRYTOWN, N.Y., Jan 15, 2008 (BUSINESS WIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) today announced the initiation of the phase 2 clinical program for PRO 140, an investigational drug for the treatment of human immunodeficiency virus (HIV) infection. Two, phase 2 clinical trials in HIV-infected individuals will investigate multiple dose levels of PRO 140 via intravenous and subcutaneous routes of administration. Intravenous PRO 140 has the potential for infrequent (e.g., monthly) dosing, whereas subcutaneous PRO 140 may enable self-administration as infrequently as every two weeks. The objective of these phase 2 studies is to identify an optimal dosing regimen of PRO 140 for evaluation in pivotal clinical trials as well as to further assess the investigational drug's safety and tolerability.

PRO 140 is a humanized monoclonal antibody directed against CCR5, a portal that most forms of HIV use to enter immune system cells. PRO 140 is a viral-entry inhibitor that is designed to protect healthy cells from infection. In a recent clinical study, single intravenous doses of PRO 140 significantly reduced HIV viral loads by greater than 90% (1.0 log₁₀) for two-to-three weeks.

"There is an urgent need for new therapies such as PRO 140 to address the limitations of currently available HIV drugs," said Paul J. Maddon, M.D., Ph.D., Progenics' Founder, Chief Executive Officer, and Chief Science Officer. "Blocking the viral-entry infection pathway with a monoclonal antibody is a promising new approach to treating people with HIV/AIDS that is designed to be more specific and better tolerated than currently available medications. Following results from these phase 2 studies, we plan to meet with the U.S. Food and Drug Administration (FDA) with the intention of moving into longer-term, pivotal trials in the first half of 2009."

In February 2006, PRO 140 was designated a Fast Track product by FDA for the treatment of HIV infection. The FDA Fast Track Development Program facilitates development and expedites regulatory review of drugs intended to address an unmet medical need for serious or life-threatening conditions. With Fast Track designation for PRO 140, Progenics can take advantage of several programs at FDA to streamline the regulatory review process and to work more closely with FDA on product development plans.

Study Design: Evaluating Infrequent Dosing

The phase 2 program includes two multi-center, double-blind, placebo-controlled studies that will be conducted in a total of 70 volunteers with early-stage HIV disease and who have not received antiretroviral therapy within the previous three months. The studies are designed to evaluate, separately, PRO 140 dosed via the intravenous or subcutaneous routes of administration. All patients will be screened prior to the study for the presence of virus that utilizes only CCR5 as the entry co-receptor. Patients will then be monitored for approximately two months to assess tolerability, antiviral activity and blood concentrations of PRO 140.

One trial is assessing intravenous PRO 140 up to 10 mg/kg. A total of 30 patients will be randomized into three groups to receive a single dose of placebo, PRO 140 5 mg/kg or PRO 140 10 mg/kg. The second trial will evaluate subcutaneous PRO 140 administered as three weekly doses or two bi-weekly (once every two weeks) doses. A total of 40 patients will be randomized into four groups to receive placebo weekly, PRO 140 162 mg weekly, PRO 140 324 mg weekly or PRO 140 324 mg biweekly. Subcutaneous PRO 140 is being developed as a potential long-acting, self-administered therapy for HIV infection.

About PRO 140

Discovered by Progenics' scientists, PRO 140 is a humanized monoclonal antibody that binds to CCR5, a co-receptor that is the principal molecular portal used by HIV to enter and infect immune system cells. In 1996, Progenics and its collaborators discovered the role of CCR5 in HIV infection.

A phase 1b clinical study completed in 2007 established proof of concept for PRO 140 as a potent antiretroviral agent with extended activity. In that phase 1b trial, patients with only CCR5-tropic virus receiving a single 5 mg/kg intravenous dose of PRO 140 achieved an average maximum decrease of viral concentrations in the blood of 98.5% (1.83 log₁₀), with individual reductions ranging up to 99.7% (2.5 log₁₀). In these patients, reductions in viral load of greater than 90% (1.0 log₁₀) on average persisted for two-to-three weeks after dosing. PRO 140 was generally well tolerated in the phase 1b clinical trial.

PRO 140 has also shown synergistic activity when combined in vitro with small-molecule CCR5 antagonists that are either approved products or are undergoing development. In vitro testing also demonstrated that PRO 140 inhibited viruses that were

resistant to small-molecule CCR5 antagonists. CCR5 is also a receptor for chemokines, members of a family of protein molecules that are secreted by cells as part of the body's natural inflammatory response. Unlike small-molecule CCR5 antagonists, PRO 140 inhibits HIV entry at concentrations that in vitro do not appear to block CCR5's natural activity, which is to direct the migration of immune cells towards sites of inflammation in the body. Therefore, PRO 140 has the potential for a better tolerability profile than small-molecule CCR5 antagonists that inhibit the functions of this receptor.

Progenics gratefully acknowledges the development funding it has received for PRO 140 from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (1 U19 AI066329).

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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 as well as the treatment of HIV infection and cancer. The Company, in collaboration with Wyeth, is developing methylnaltrexone for the treatment of opioid-induced side effects, including constipation (oral and subcutaneous formulations) and post-operative bowel ileus (intravenous formulation). In March 2007, the Company submitted a New Drug Application to the United States Food and Drug Administration for the subcutaneous formulation of methylnaltrexone for patients suffering from opioid-induced constipation while receiving palliative care, followed in May 2007 by Wyeth's submission of a Marketing Authorization Application (MAA) in Europe to the European Medicines Agency (EMA). In the area of HIV infection, the Company is developing the viral-entry inhibitor PRO 140, a humanized monoclonal antibody targeting the HIV entry co-receptor CCR5, which has completed phase 1b clinical studies with positive results. In the area of prostate cancer, the Company is developing a human monoclonal antibody drug conjugate - a selectively targeted cytotoxic antibody directed against prostate-specific membrane antigen (PSMA), a protein found on the surface of prostate cancer cells. Progenics is also developing vaccines designed to stimulate an immune response to PSMA.

DISCLOSURE NOTICE: The information contained in this document is current as of January 15, 2007. This press release contains forward-looking statements. Any statements contained herein that are not statements of historical fact may be forward-looking statements. When the Company uses the words "anticipates" "plans" "expects" and similar expressions, it is identifying forward-looking statements. Such forward-looking statements involve risks and uncertainties which may cause the Company's actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. Such factors include, among others, the uncertainties associated with product development, the risk that clinical trials will not commence or proceed as planned, the risks and uncertainties associated with dependence upon the actions of our corporate, academic and other collaborators and of government regulatory agencies, the risk that our licenses to intellectual property may be terminated because of our failure to have satisfied performance milestones, the risk that products that appear promising in early clinical trials do not demonstrate efficacy in larger-scale clinical trials, the risk that we may not be able to manufacture commercial quantities of our products, the uncertainty of future profitability and other factors set forth more fully in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and other reports filed with the Securities and Exchange Commission, to which investors are referred for further information. In particular, the Company cannot assure you that any of its programs will result in a commercial product.

Progenics does not have a policy of updating or revising forward-looking statements and assumes no obligation to update any forward-looking statements contained in this document as a result of new information or future events or developments. Thus, it should not be assumed that the Company's silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

Editor's Note:

Additional information on Progenics available at <http://www.progenics.com>

Progenics' PRO 140 animations can be viewed at <http://www.progenics.com/ani2.cfm>

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