Progenics Pharmaceuticals Completes Enrollment in Phase 3 Study of PSMA-Targeted Imaging Agent 1404

January 2, 2018

Top-line Data Expected in 3Q2018

NEW YORK, Jan. 02, 2018 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (NASDAQ:PGNX), an oncology company developing innovative medicines and imaging analytical tools for targeting and treating cancer, today announced that it has completed enrollment in its Phase 3 study of 1404, a PSMA-targeted small molecule SPECT/CT imaging agent that is designed to visualize prostate cancer.

"The results of this large-scale Phase 3 study will provide important insights on the potential of our novel imaging agent to accurately and non-invasively detect and monitor patients with low-grade prostate cancer," said Mark Baker, Chief Executive Officer of Progenics. "We believe that 1404 has the possibility to transform the practice of active surveillance, and we look forward to providing top-line results in the third quarter."

The Phase 3 study enrolled approximately 450 patients in the U.S. and Canada with newly-diagnosed or low-grade prostate cancer, whose biopsy indicates a histopathologic Gleason grade of ≤ 3+4 severity and/or are candidates for active surveillance. The study was designed to evaluate the specificity of 1404 imaging to identify patients without clinically significant prostate cancer and sensitivity to identify patients with clinically significant disease.

About 1404, an Imaging Compound Targeting Prostate Specific Membrane Antigen

Progenics' molecular imaging radiopharmaceutical product candidate 1404 targets the extracellular domain of prostate specific membrane antigen (PSMA), a protein amplified on the surface of > 95% of prostate cancer cells and a validated target for the detection of primary and metastatic prostate cancer. 1404 is labeled with Technetium-99m, a gamma-emitting isotope that is widely available, is easy to prepare, and is attractive for nuclear medicine imaging applications. The image created provides the opportunity to visualize cancer, potentially allowing for improved detection and staging, more precise biopsies, and a targeted treatment plan including active surveillance as a disease management tool.

About Prostate Cancer

Prostate cancer is the second most common form of cancer affecting men in the United States: an estimated one in seven men will be diagnosed with prostate cancer in his lifetime. The American Cancer Society estimates that each year approximately 161,360 new cases of prostate cancer will be diagnosed and about 26,730 men will die of the disease. Approximately 2.9 million men in the U.S. currently count themselves among prostate cancer survivors.

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® and 1095), 2) PSMA-targeted imaging agents for prostate cancer (1404 and PyL™), and 3) imaging analysis tools. Progenics' first commercial product, RELISTOR® (methylnaltrexone bromide) for opioid-induced constipation, is partnered with Valeant Pharmaceuticals International, Inc.

This press release may contain 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, such as the Phase 3 clinical program for 1404; our ability to successfully develop and commercialize the products of EXINI Diagnostics AB; the unpredictability of the duration and results of regulatory review of New Drug Applications (NDA) and Investigational NDAs, including our NDA for AZEDRA and related inspections of Progenics' and its contract manufacturing organizations' facilities and other sites and other requirements that will need to be met before any approval is obtained; market acceptance for approved products; the effectiveness of the efforts of our partners to market and sell products on which we collaborate and the royalty revenue generated thereby; generic and other competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, as updated in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 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.
(PGNX-F)

Contact:
Melissa Downs
Investor Relations

(646) 975-2533
mdowns@progenics.com

Primary Logo

Source: Progenics Pharmaceuticals Inc.