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Progenics Pharmaceuticals Announces First Patient Dosed in Phase 2/3 Clinical Trial of PSMA-Targeted PET/CT Imaging Agent PyL™

Study to Enroll 300 Patients in U.S. and Canada

NEW YORK, Dec. 07, 2016 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX), an oncology company developing innovative medicines and other products for targeting and treating cancer, today announced that the first patient has been dosed in the Company's Phase 2/3 clinical trial evaluating the diagnostic accuracy of its PSMA-targeted PET/CT imaging agent, 18F-DCFPyL (PyL™). PyL was discovered by a team led by Martin G. Pomper, M.D., Ph.D., William R. Brody Professor of Radiology at the Center for Translational Molecular Imaging at the Johns Hopkins University School of Medicine.

"There exists a significant need for approved molecular imaging modalities with both high sensitivity and specificity to detect high risk recurrent or metastatic prostate cancer early," said Lawrence Saperstein, M.D., Assistant Professor, Department of Radiology and Biomedical Imaging, Chief, Nuclear Medicine Program Director, Nuclear Radiology Fellowship, Yale University School of Medicine, where the first patient was dosed. "We believe PyL, when used with a PET/CT scan, can provide treating physicians with more accurate disease detection, potentially leading to earlier diagnoses, more informed treatment decisions as well as the ability to monitor responses, and ultimately improved patient outcomes."

The Phase 2/3 study will enroll approximately 300 patients with high risk prostate cancer with recurrence or metastatic disease in the United States and Canada. Primary endpoints of the study include the assessment of sensitivity and specificity of PyL PET/CT imaging to detect prostate cancer in the prostate gland and regional lymph nodes, as well as sensitivity in sites of metastasis or recurrence. Secondary endpoints include safety and tolerability, detection rate, and pharmacokinetic parameters.

"This trial initiation represents a significant milestone for our PyL program, and is designed to help support registration of this novel imaging agent," stated Mark Baker, Chief Executive Officer of Progenics. "The early clinical data for PyL have been quite impressive, underscoring its potential to transform disease management for prostate cancer, and we look forward to further demonstrating its diagnostic performance as we advance the trial."

About PyL for PET Imaging of Prostate Cancer

PyL (also known as 18F-DCFPyL) is a clinical-stage, fluorinated PSMA-targeted PET imaging agent for prostate cancer that was discovered and developed at the Center for Translational Molecular Imaging at the Johns Hopkins University School of Medicine. A proof-of-concept study published in the April 2015 issue of the Journal of Molecular Imaging and Biology demonstrated that PET imaging with PyL showed high levels of PyL uptake in sites of putative metastatic disease and primary tumors, while rapidly clearing from other organs, suggesting the potential for high sensitivity and specificity in detecting prostate cancer while appearing to be safe and well tolerated.

About Progenics

Progenics Pharmaceuticals, Inc. is developing innovative medicines and other products for targeting and treating cancer, with a pipeline that includes several product candidates in later-stage clinical development. These products in development include therapeutic agents designed to precisely target cancer (AZEDRA® and 1095), and PSMA-targeted imaging agents for prostate cancer (1404 and PyL™) intended to enable clinicians and patients to accurately visualize and manage their disease. In addition, in late 2015 Progenics acquired EXINI Diagnostics AB, a leader in the development of advanced artificial intelligence-based imaging analysis tools and solutions for medical decision support. The acquisition of EXINI complements Progenics' strategy to support its imaging and therapeutic agents with sophisticated analytical tools and other technologies to help physicians and patients visualize, understand, target and treat cancer. Progenics' first commercial product, RELISTOR® (methylnaltrexone bromide) for opioid-induced constipation, is partnered with and marketed by 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 our collaboration with Valeant on the RELISTOR oral formulation and the Phase 3 clinical program for 1404; our ability to successfully integrate EXINI Diagnostics AB and to develop and commercialize its products; the unpredictability of the duration and results of regulatory review of New Drug Applications and Investigational NDAs; 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 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. 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. Please follow us on LinkedIn®. Information on or accessed through our website or social media sites is not included in the company's SEC filings.

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