Progenics Pharmaceuticals Completes Enrollment of Phase 2/3 Clinical Trial of PSMA-Targeted PET/CT Imaging Agent PyL™ in Prostate Cancer

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Top-line Data Expected in 4Q2018

NEW YORK, June 26, 2018 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX), an oncology company developing innovative medicines and imaging technology for targeting and treating cancer, today announced that it has completed enrollment in its Phase 2/3 OSPREY clinical trial evaluating the diagnostic accuracy of its PSMA-targeted PET/CT imaging agent, PyL™ (18F-DCFPyL), in prostate cancer.

"The completion of enrollment for our PyL trial, ahead of schedule, marks an important milestone for the advancement of our PSMA-targeted pipeline," said Mark Baker, Chief Executive Officer of Progenics. “PyL is a PSMA-targeted PET imaging agent that has the potential to transform how physicians manage and treat prostate cancer from time of initial diagnosis to metastatic or recurrent disease; it has the potential to detect very small bone and soft tissue metastases at earlier stages in the disease progression. We look forward to reporting top-line data from the trial in the fourth quarter of 2018 while initiating a second Phase 3 study of PyL in patients with biochemical recurrence of prostate cancer by year end.”

The OSPREY study enrolled 266 patients with localized high risk prostate cancer and 117 patients with recurrent or metastatic disease in the United States and Canada for a total of 383 patients. The study’s co-primary endpoints include the assessment of sensitivity and specificity of PyL PET/CT imaging to detect prostate cancer in regional lymph nodes in patients scheduled to undergo radical prostatectomy. Secondary endpoints include sensitivity within sites of metastasis or recurrence, and other diagnostic performance characteristics, pharmacokinetic parameters, and safety and tolerability.

About PyL™ for PET Imaging of Prostate Cancer

PyL (also known as [18F]DCFPyL) is a fluorinated PSMA-targeted Positron Emission Topography (“PET”) imaging agent that enables visualization of both bone and soft tissue metastases to determine the presence or absence of recurrent and/or metastatic prostate cancer.

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

This press release contains 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; the unpredictability of the duration and results of regulatory review of New Drug Applications (NDA) and Investigational NDAs, including our NDA for AZEDRA; market acceptance for approved products; 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 Annual Report on Form 10-K for the annual period ended December 31, 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.

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