Progenics Pharmaceuticals Completes Enrollment in Pivotal Phase 3 CONDOR Study of PyL for the Detection of Prostate Cancer

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Top-line Data Now Expected by Year End

Reaches Alignment with FDA on Regulatory Path; Company to Submit NDA Following Positive CONDOR Data

Completed Enrollment in Pivotal Phase 3 Trial in Eight Months

NEW YORK, Aug. 05, 2019 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (NASDAQ:PGNX), an oncology company developing innovative targeted medicines and artificial intelligence to find, fight and follow cancer, today announced that it has completed enrollment five months ahead of schedule in the Company's Phase 3 CONDOR study evaluating the diagnostic performance and clinical impact of PyL™ (^{18}F-DCFPyL) in men with biochemical recurrence of prostate cancer. PyL is the Company's PSMA-targeted small molecule PET/CT imaging agent designed to visualize prostate cancer.

The Company also reported that it recently met with the U.S. Food and Drug Administration (FDA) to discuss the regulatory path for PyL. Based on those discussions, the Company believes that positive data from the CONDOR study and the previously reported OSPREY study could serve as the basis for a regulatory submission. Progenics intends to submit a New Drug Application (NDA) with the FDA for PyL following the Phase 3 CONDOR study, assuming positive results.

"We have made significant progress with our PyL program in recent months on both the clinical and regulatory fronts, demonstrating our ability to execute complex, multi-center studies under ambitious timelines," said Vivien Wong, Ph.D., Executive Vice President, R&D, of Progenics. "The accelerated enrollment completion in our Phase 3 CONDOR study underscores the clinical interest in our PSMA-targeted imaging agent and the need for better diagnostic options for patients with biochemical recurrent prostate cancer."

Dr. Wong continued, "We believe that PyL has the potential to alter physician treatment plans and improve patient outcomes through the detection of small nodal and metastatic lesions that are missed by currently available conventional imaging modalities. Currently, over 1,000 men with prostate cancer have been imaged with PyL in the clinical setting. We look forward to rapidly advancing this program toward NDA submission and commercialization following positive CONDOR data. We are grateful to the patients and their caregivers who participated in the trial, and to the investigators and their study staff for their extraordinary efforts in executing this study ahead of schedule."

The Phase 3 CONDOR study is a multi-center, open label study that dosed 208 patients with biochemical recurrence of prostate cancer at 14 sites in the United States and Canada. The primary endpoint is based on positive predictive value and will assess the correct localization rate (CLR), defined as a percentage of subjects with a one-to-one correspondence between localization of at least one lesion identified by PyL and the composite truth standard. Secondary measures include the percentage of subjects with a change in intended prostate cancer treatment plans due to PyL PET/CT imaging.

About PyL™ for PET Imaging of Prostate Cancer

PyL (also known as ^{18}F-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. Progenics initiated patient dosing of the Phase 3 study evaluating the diagnostic performance and clinical impact of PyL in November 2018. The last patient visit is expected in September and top-line data is expected by year end.

PyL and 1095

The multicenter, randomized, open-label, controlled Phase 2 clinical study is evaluating the efficacy and safety of I-131-1095 in combination with enzalutamide compared to enzalutamide alone in patients with mCRPC who are PSMA-avid, chemotherapy naïve, and progressed on abiraterone. PSMA-avidity is determined utilizing PyL imaging which enrich for patients who are most likely to respond to 1095 therapy, highlighting the synergistic potential of our PSMA-targeted pipeline to better diagnose and treat prostate cancer. Based on the early data from this open-label study and dialogue with the FDA, we plan to evaluate initiating a pivotal trial of 1095 in 2020.

About Prostate Cancer

Prostate cancer is the second most common form of cancer affecting men in the United States: an estimated one in nine men will be diagnosed with prostate cancer in his lifetime. The American Cancer Society estimates that each year approximately 174,650 new cases of prostate cancer will be diagnosed and about 31,620 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 is an oncology company focused on the development and commercialization of innovative targeted medicines and artificial intelligence to find, fight and follow cancer, including: therapeutic agents designed to treat cancer (AZEDRA®, 1095, and PSMA TTC); prostate-specific membrane antigen ("PSMA") targeted imaging agents for prostate cancer (PyL™ and 1404); and imaging analysis technology (aBSI and PSMA AI). Progenics has two commercial products, AZEDRA, for the treatment of patients with unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (rare neuroendocrine tumors of neural crest origin) who require systemic anticancer therapy; and RELISTOR® (methylnaltrexone bromide) for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies 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 and include statements regarding Progenics' strategic and operational plans and delivering value for shareholders. 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: market acceptance for approved products; the risk that the commercial launch of AZEDRA may not meet revenue and income expectations; 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; the inherent uncertainty of outcomes in the intellectual property disputes such as the dispute with the University of Heidelberg regarding PSMA-617; our ability to successfully develop and commercialize products that incorporate licensed intellectual property; 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; the costs and management distraction attendant to activist shareholder campaigns; and risks related to potential changes in the composition of our Board of Directors following our 2019 Annual Meeting of Shareholders. 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 Securities and Exchange Commission (the "SEC"), including those risk factors included in its Annual Report on Form 10-K for the year ended December 31, 2018, as updated in its subsequent Quarterly Reports on Form 10-Q. 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 press 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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