Progenics Pharmaceuticals Announces Phase 3 CONDOR Trial of PyL™ in Prostate Cancer Achieved Primary Endpoint

December 23, 2019

- Met Primary Endpoint With a Correct Localization Rate of 84.8–87.0%, Highlighting Strong Diagnostic Performance
- Company Expects to Submit an NDA to the FDA in the Second Half of 2020
- Conference Call at 8:00 AM Eastern Time

NEW YORK, Dec. 23, 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 positive top line results from the Phase 3 CONDOR trial 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 positron emission tomography (PET) imaging agent designed to visualize prostate cancer.

"There is a need for improved diagnostics for prostate cancer to replace conventional imaging tests that have limited performance characteristics, especially in men with biochemical recurrence of their disease," said Barry Siegel, MD, Professor of Radiology at Washington University School of Medicine in St. Louis. "The high positive predictive value demonstrated in this study reflects the clinical utility of PSMA-targeted PET imaging agents providing actionable information to physicians to guide treatment plans and improve disease management of one of the most prevalent cancers in the U.S."

The Phase 3 CONDOR trial is a prospective, multi-center, open label pivotal trial in which 208 patients with biochemical recurrence of prostate cancer and uninformative baseline imaging based on conventional modalities (i.e. Axumin, Choline PET, CT/MR and/or bone scan) were dosed and imaged with PyL at 14 sites in the United States and Canada. The CONDOR trial achieved its primary endpoint, with a correct localization rate (CLR) of 84.8% to 87.0% among the three blinded independent readers (the lower bound of the 95% confidence intervals ranging from 77.8% to 80.4%). CLR is based on positive predictive value, defined as the percentage of patients with a one-to-one correspondence between localization of at least one lesion identified on ^{18}F-DCFPyL PET/CT and a composite truth standard comprised of histopathology, conventional imaging and/or changes in PSA levels following radiation therapy.

Safety results showed PyL was well tolerated, consistent with the Phase 2 OSPREY trial results. There was one serious adverse event of hypersensitivity reported in one patient as related to the study drug. The most frequent adverse event reported was headache, which was reported in four patients (1.9% of the trial population).

"The positive results of our Phase 3 CONDOR trial reinforce our belief in the potential of PyL to enable better physician treatment decisions and, ultimately, improve patient outcomes. The rapid trial enrollment and physician support further underscore the excitement and positive reception of PyL as a new addition in the fight against prostate cancer and, together with the commercial performance of diagnostic agents in use today, reinforce our belief in the significant market opportunity for PyL," said David Mims, Interim CEO. "Based on these positive results, we plan to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for PyL in the second half of 2020."

Additional results from the CONDOR trial are expected to be presented at an upcoming medical meeting.

Investor Conference Call
Progenics will host a conference call today at 8:00 AM Eastern Time to discuss the results. The live and replayed webcast of the call will be available through the Company's website at www.progenics.com. To participate in the live call by phone, dial (877) 250-8889 (USA) or (720) 545-0001 (international) and enter the passcode 9165086. The replay of the call will be available for 90 days.

About PyL™ for PET Imaging of Prostate Cancer
PyL (also known as ^{18}F-DCFPyL) is a fluorinated PSMA-targeted positron emission tomography ("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 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 three 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 oral and subcutaneous formulations of RELISTOR® (methylnaltrexone bromide) for the treatment of opioid-induced constipation, which are partnered with Bausch Health Companies Inc.

Forward Looking Statements
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: risks associated with the proposed merger transaction with Lantheus Holdings, Inc.; 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; and risks related to changes in the composition of our Board of Directors following the delivery of shareholder consents in response to the recent consent solicitation conducted by one of our 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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Contact
Melissa Downs
Investor Relations
(646) 975-2533
mdowns@progenics.com