Progenics to Present Results from the Phase 3 CONDOR Trial of PyL™ (18F-DCFPyL) in Prostate Cancer at the American Society of Clinical Oncology 2020 Virtual Scientific Program

May 18, 2020

- Met Primary Endpoint with a Correct Localization Rate of 84.8–87.0% -
- 63.9% Change in Disease Management Plan Based on PyL Imaging Results -
- Planned NDA Submission On Track for Early Third Quarter 2020 -

NEW YORK, May 18, 2020 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX), an oncology company developing innovative medicines and artificial intelligence to find, fight and follow cancer, today announced that the 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 will be presented in an oral session at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program. PyL is the Company's PSMA-targeted small molecule positron emission tomography (PET) imaging agent designed to visualize prostate cancer.

"The vast majority of men dying of prostate cancer, the second most common cause of cancer-related death in men, succumb to metastatic disease. Due to the limitations of conventional imaging, early detection and accurate localization of metastatic lesions in patients with biochemical recurrence of prostate cancer represents an important medical need," said Peter R. Carroll, M.D., M.P.H., Distinguished Professor, Department of Urology, University of California, San Francisco. "New imaging agents, such as PyL, that enable early identification of metastatic disease, both at initial staging and at any point after definitive therapy, could have the potential to impact patient outcomes."

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, including 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 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 (PPV), defined as the percentage of patients with a one-to-one correspondence between localization of at least one lesion identified on PyL and a composite truth standard comprised of histopathology, conventional imaging and/or a ≥ 50% decline in PSA levels following radiation therapy. Median CLR in patients with baseline PSA <0.5 ng/mL, 0.5 to <1.0 ng/mL, and 1.0 to <2.0 ng/mL were 73.3%, 75.0%, and 83.3%, respectively, which are promising results in a patient population with non-informative baseline findings based on available approved imaging modalities.

63.9% of patients in the CONDOR trial had a change in intended disease management plans due to PyL imaging results, a key secondary endpoint of the trial. The most frequent changes to treatment management plans due to the PyL results included salvage local therapy to systemic therapy, observation to initiating therapy, noncurative systemic therapy to salvage local therapy, and planned treatment to observation.

"In addition to the robust diagnostic performance, the clinician's high change in management rate based on PyL scans is a particularly significant finding of CONDOR. The subjects in this study represent a true clinical dilemma as there is residual disease present as demonstrated by the detectable PSA, but standard scans are uninformative. CONDOR demonstrates that clinicians trust the information on the PyL scan and use it," said Michael J. Morris, M.D., Clinical Director, Genitourinary Medical Oncology Service & Prostate Cancer Section Head, Division of Solid Tumor Oncology, Memorial Sloan Kettering Cancer Center, and lead author of the ASCO presentation. "These positive results further underscore the diagnostic potential for PSMA targeted imaging and open up future opportunities to examine how the results of PyL imaging can be used to deliver new, improved patterns of care."

Consistent with the Phase 2 OSPREY trial results, safety results showed that PyL was well tolerated. There was one serious adverse event of hypersensitivity reported as related to the study drug in a patient with significant allergic history.

"The full positive results of our Phase 3 CONDOR trial continue to validate our beliefs in PyL to potentially alter the way physicians treat prostate cancer. The CONDOR results, together with previously presented data from OSPREY, collectively demonstrated strong diagnostic performance of PyL in multiple stages of the prostate cancer disease continuum," said David Mims, Interim Chief Executive Officer of Progenics. "We remain on track to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for PyL early in the third quarter of 2020."

Details for the ASCO 2020 Virtual Scientific Program presentation are as follows:

Title: Impact of PSMA-targeted imaging with 18F-DCFPyL-PET/CT on clinical management of patients (pts) with biochemically recurrent (BCR) prostate cancer (PCa): Results from a phase III, prospective, multicenter study (CONDOR)
Presenter: Michael J. Morris, M.D., Clinical Director, Genitourinary Medical Oncology Service & Prostate Cancer Section Head, Division of Solid Tumor Oncology, Memorial Sloan Kettering Cancer Center
Abstract #: 5501
Session: Genitourinary Cancer—Prostate, Testicular, and Penile
Date and Time: May 29, 2020 at 8 AM ET on an "on demand" basis

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 coronavirus (COVID-19) pandemic and the measures taken to prevent its spread and the related impact on our business; 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 intellectual property disputes such as the dispute with 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; and 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 (SEC), including those risk factors included in its Annual Report on Form 10-K for the year ended December 31, 2019, 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 Progenics' SEC filings.

(PGNX-F)

Contact
Melissa Downs
Investor Relations
(646) 975-2533
mdowns@progenics.com