Progenics Reports Results of Phase 2/3 Trial of PSMA PET Imaging Agent PyL for the Detection of Prostate Cancer

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-PyL highly sensitive, 93-99%, in reliably detecting metastatic prostate cancer lesions and highly specific, 96-99%, in confirming the absence of pelvic lymph node disease-

-Study data highlights the strong positive predictive values of PyL to detect prostate cancer in pelvic lymph nodes and metastatic lesions and supports continued development of PyL-

-Phase 3 trial to commence by year end-

-Conference Call at 8:30 AM Eastern Time-

NEW YORK, Oct. 05, 2018 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (NASDAQ:PGNX), an oncology company developing innovative medicines and imaging analysis technology for targeting and treating cancer, today announced data from its OSPREY 2301 Study of PyL™ (18F-DCFPyL). PyL is the Company's PSMA-targeted small molecule PET imaging agent designed to visualize prostate cancer. In the study, PyL demonstrated high sensitivity in reliably detecting distant metastatic prostate cancer lesions and high specificity in confirming the absence of pelvic lymph node disease. The associated strong positive predictive values and negative predictive value of PyL imaging in these disease settings indicate its potential high clinical utility.

Dr. Michael Morris, Associate Professor at Memorial Sloan Kettering, and a lead investigator of the trial said "these are highly encouraging results in a large, well-controlled and rigorous trial showing PyL has excellent positive and negative predictive value in assessing the distribution of disease in men with high-risk prostate cancer. Furthermore, in men intended to go to surgery, the specificity of PyL was exceedingly good. Taken together, a PyL PET avid lesion is a reliable reflection of histologically proven disease and may provide additional important information to men with prostate cancer and their doctors. That information may provide important guidance in the decision-making for their treatment."

Phase 2/3 Trial Results

The trial examined the diagnostic performance of PSMA-targeted PET imaging agent, PyL, to detect prostate cancer in pelvic lymph nodes in patients with high risk locally advanced prostate cancer (Cohort A) and distant metastases in patients with metastatic or recurrent (Cohort B) prostate cancer. The diagnostic performance of PyL PET imaging in this "gold standard" trial was evaluated against histopathology as the standard of truth. The OSPREY study dosed 385 patients with either high-risk locally advanced prostate cancer (268) or metastatic or recurrent prostate cancer (117). The study's co-primary endpoints were the assessment of specificity and sensitivity of PyL PET imaging in Cohort A to detect prostate cancer in pelvic lymph nodes in patients scheduled to undergo radical prostatectomy with extended pelvic lymph node dissection. Key secondary endpoints for Cohort A were positive predictive value and negative predictive value. The study also evaluated several key secondary endpoints in Cohort B, including the sensitivity and positive predictive value of PyL PET imaging in detecting metastatic prostate cancer in patients where lesion biopsies (bone, soft tissues, lymph nodes other than pelvic lymph nodes) were feasible.

In the trial, the diagnostic performance of PyL in detecting disease in pelvic lymph nodes (Cohort A) showed a high specificity (96-99% among the three blinded independent readers), meeting the first co-primary endpoint of the trial, with the lower bound of the 95th percent confidence interval (94-96%) exceeding 80%. The sensitivity of 31-42%, did not meet the second co-primary endpoint, as the lower bound of the 95th percentile confidence interval (19-30%) did not exceed the required 40%. The positive predictive value and negative predictive value of pelvic lymph node detection were 78-91% and 81-84%, respectively.

In the metastatic or recurrent prostate cancer setting (Cohort B), PyL exhibited sensitivity of 93-99% and PPV of 81-88% in detecting metastatic lesions. Specificity and negative predictive value were not endpoints specified in the protocol for Cohort B as all men in Cohort B were suspected to have disease.

18F-DCFPyL was very well tolerated. A total of 27 (7%) subjects experienced at least one treatment related adverse event. There were no serious adverse events related to study drug. The most frequent drug related events included dysgeusia (2.1%) and headache (2.1%).

"The data from this trial shows the strength of PyL in prostate cancer detection, and its potential to be highly valuable for disease and treatment monitoring," said Dr. Vivien Wong, Executive Vice President of Development at Progenics. "While specificity and sensitivity are often used to describe diagnostic performance, PPV and NPV are increasingly considered more relevant indicators of actual clinical utility. Following our discussions with FDA, our Phase 3 trial design will use a primary endpoint based on PPV parameters in the biochemical recurrence setting."

"PyL imaging holds great promise in transforming how physicians manage and treat high risk, metastatic, and recurrent prostate cancer," said Mark Baker, Chief Executive Officer of Progenics. "Our data from OSPREY provides strong rationale for continued development, and we look forward to launching our Phase 3 trial by year-end."

Progenics plans to submit the full results from the trial for presentation at a medical meeting.

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.

Investor Conference Call

Progenics will host a conference call today at 8:30 AM Eastern Time to discuss the approval. 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 4282148. The replay of the call will be available for 90 days.

About Prostate Cancer

Prostate cancer is the second most common form of cancer affecting men in the United States: an estimated one in seven men will be diagnosed with prostate cancer in his lifetime. The American Cancer Society estimates that each year approximately 161,360 new cases of prostate cancer will be diagnosed and about 26,730 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 develops innovative medicines and other technologies to target and treat cancer, including: therapeutic agents designed to treat cancer (AZEDRA®, 1095, and PSMA TTC); prostate-specific membrane antigen (“PSMA”) targeted imaging agents for prostate cancer (1404 and PyL); and imaging analysis technology. Progenics has two commercial products, RELISTOR® (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid-induced constipation, which is partnered with Salix Pharmaceuticals, Inc. (a wholly-owned subsidiary of Bausch Health Companies Inc. (formerly known as Valeant Pharmaceuticals International, Inc.)); and 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.

This press release contains "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 are generally 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 cost, timing and unpredictability of results of clinical trials and other development activities and collaborations, such as the anticipated launch of a Phase 3 trial for PyL; our ability to successfully develop and commercialize products, such as PyL, 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. 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 fiscal year ended December 31, 2017, 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 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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