Progenics Doses First Patient in Pivotal Phase 3 Study of PyL, PSMA PET Imaging Agent, for the Detection of Prostate Cancer

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-Potential to Improve Early Detection and Transform the Treatment Landscape for Recurrent Prostate Cancer -

NEW YORK, Dec. 03, 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 that the first patient has been dosed 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.

Dr. Lawrence Saperstein, Assistant Professor of Radiology and Biomedical Imaging and Chief of Nuclear Medicine at Yale Smilow Cancer Hospital, and a principle investigator of the trial said, "PyL has demonstrated excellent positive and negative predictive values in detecting the presence or absence of prostate cancer. This valuable information has the potential to provide earlier diagnoses, more informed treatment decisions, the ability to monitor responses, and ultimately improve patient outcomes."

The Phase 3 CONDOR trial is a multi-center, open label study and will enroll approximately 200 patients with biochemical recurrence of prostate cancer in 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.

"The initiation of this landmark trial marks an important milestone in the development of PSMA-targeted imaging agents which have the potential to transform the treatment landscape for recurrent prostate cancer," stated Mark Baker, CEO of Progenics. "With PyL, physicians may be able to detect very small lesions that are currently missed with conventional imaging methods, which in turn could change the treatment path. We look forward to reporting data from this trial in early 2020."

In prior studies, PyL has shown strong positive predictive value to detect prostate cancer, with high sensitivity (93-99%) in reliably detecting metastatic prostate cancer lesions and high specificity (96-99%) in confirming the absence of pelvic lymph node disease.

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.

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 164,690 new cases of prostate cancer will be diagnosed and about 29,430 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 agent for prostate cancer (PyL); and imaging analysis technology. 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) subcutaneous injection for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies Inc.

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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