Progenics Pharmaceuticals Doses First Patient in Phase 2 Clinical Study of 1095 Radiotherapy for the Treatment of Metastatic Prostate Cancer

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NEW YORK, June 13, 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 the first patient has been dosed in the Company's Phase 2 clinical study evaluating I-131 1095 radiotherapy in combination with enzalutamide for the treatment of metastatic castration resistant prostate cancer (mCRPC). 1095 is the Company's small molecule radiotherapeutic designed to selectively bind to the extracellular domain of prostate specific membrane antigen (PSMA).

"1095 radiotherapy represents a targeted treatment option for prostate cancer with a new mechanism of action that may overcome resistance developed to novel androgen axis drugs, such as abiraterone and enzalutamide," said Dr. David Laidley, Nuclear Medicine Physician at London Health Sciences Centre (LHSC) and Scientist at Lawson Health Research Institute, the research institute of LHSC and St. Joseph's Health Care London in Ontario, Canada. "The growing resistance to these anti-androgen drugs in the pre-chemotherapy patient population further reinforces the unmet need for novel targeted therapies."

The multicenter, randomized, open-label, controlled Phase 2 clinical study is evaluating the efficacy and safety of 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™ (^{18}F-DCFPyL), the Company's PET imaging agent in clinical development designed to visualize prostate cancer. The trial is expected to enroll approximately 120 patients at 25 sites in the U.S. and Canada. The study's primary endpoint is prostate specific antigen (PSA) response rate according to Prostate Cancer Clinical Trials Working Group 3 (PCWG3) criteria defined as a confirmed 50% or greater decline from baseline. Key secondary endpoints evaluate radiographic response based on Response Evaluation Criteria In Solid Tumors (RECIST) for soft tissue or PCWG3 for bone, progression free survival (PFS), and overall survival (OS). Patients will be followed for one year after their first treatment for all efficacy endpoints. Survival and safety data will be collected for an additional year.

"The commencement of patient dosing in our Phase 2 clinical study is a significant step forward for the development of 1095, which has the potential to treat metastatic patients at an earlier stage utilizing a differentiated, PSMA-targeted approach. Data from a compassionate use study has already demonstrated 1095's potential with marked reduction of PSA and bone pain in a group of heavily pretreated advanced prostate cancer patients and was well tolerated. Recent preclinical data suggest enzalutamide could sensitize cells to radiotherapy induced cell death, providing the preclinical rationale for the combination of radiotherapy and enzalutamide to represent a potentially more effective treatment paradigm for patients with mCRPC," said Asha Das, M.D., Chief Medical Officer of Progenics. "The 1095 study design includes the use of PyL imaging to screen for PSMA avidity and 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 1095

Progenics' small molecule therapeutic candidate 1095 is designed to bind with high affinity to the extracellular domain of prostate specific membrane antigen (PSMA), a protein that is highly expressed in prostate cancer cells. Once bound, 1095 is internalized by the prostate cancer cells, where the beta radiation emitted by iodine-131 kills the malignant cell. This ability to deliver targeted radiation systemically to PSMA expressing cancer cells represents a novel therapeutic mechanism of action to treat prostate cancer. When studied in a compassionate use setting, 1095 markedly reduced PSA and bone pain in a group of heavily pre-treated advanced prostate cancer patients.

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 a Phase 3 study evaluating the diagnostic performance and clinical impact of PyL in November 2018. The Phase 3 CONDOR trial is a multi-center, open label trial that will enroll approximately 200 male patients with biochemical recurrence of prostate cancer in 14 sites in the United States and Canada. The Company expects to complete enrollment in the fourth quarter of 2019 and report data in early 2020.

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 agent for prostate cancer (PyL™); 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.

About Lawson Health Research Institute

As the research institute of London Health Sciences Centre and St. Joseph's Health Care London, and working in partnership with Western University, Lawson Health Research Institute is committed to furthering scientific knowledge to advance health care around the world. For more information please visit www.lawsonresearch.ca

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. 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. 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 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 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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