



## **Data Presented at the 2019 American Urological Association (AUA) Annual Meeting Showcases Potential for Progenics' PyL Imaging Agent**

May 6, 2019

*-Phase 2/3 OSPREY Data Demonstrates PyL's High Specificity and Sensitivity in Detecting Prostate Cancer-*

*-Data Generated Under PyL Research Access Program Supports Potential of PyL to Detect Disease in Biochemical Recurrent Patients, Including Those with Low PSA Scores, and Impact Clinical Management-*

NEW YORK, May 06, 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 data highlighting the potential of its PyL imaging agent was featured in two oral presentations at the 2019 American Urological Association (AUA) Annual Meeting in Chicago, Illinois. The data presented included the results from the Company's Phase 2/3 OSPREY trial evaluating PyL in prostate cancer, as well as results from an investigator-sponsored study conducted under the Company's PyL Research Access Program™ that evaluated PyL in patients with biochemical recurrent prostate cancer. PyL is the Company's PSMA-targeted small molecule PET/CT imaging agent designed to visualize prostate cancer.

The data presented highlights the potential of PyL to detect prostate cancer in locally-advanced prostate cancer, biochemically recurrent prostate cancer, and metastatic disease, including data from the investigator-sponsored study which shows PyL imaging has the potential to change clinical management in nearly two thirds of biochemically recurrent prostate cancer patients.

"Collectively, the data presented at AUA highlights the potential of PyL to transform how prostate cancer is staged, monitored and treated," stated Asha Das, M.D., Chief Medical Officer of Progenics. "In these studies, PyL detects small, locoregional and distant metastatic lesions not currently visible by traditional imaging modalities, even in patients presenting with low PSA values. In addition, we continue to see data showing PyL imaging can drive changes in clinical management. We believe that PyL offers significant advantages over conventional imaging modalities, which could translate into the potential for earlier diagnoses, more informed treatment decisions, and the ability to monitor responses to treatment. We look forward to further advancing the development of PyL through our ongoing Phase 3 CONDOR trial and gaining additional insights on its clinical utility through the PyL Research Access Program."

Details on the data presentations are included below.

### **Phase 2/3 OSPREY Trial Data**

The OSPREY trial was designed to determine the diagnostic performance of PyL to detect prostate cancer in both pelvic lymph nodes in patients with high risk prostate cancer, and in correctly localizing sites of metastases in patients with recurrent or metastatic prostate cancer.

Safety data showed PyL was well-tolerated and safe in all patients, with no drug-related serious adverse events reported. The most frequent adverse reactions were dysgeusia and headache.

Michael Gorin, M.D., Assistant Professor of Urology at the Johns Hopkins School of Medicine and a Lead Investigator for the OSPREY trial, stated, "Conventional imaging approaches are not sufficiently sensitive or specific enough to detect early prostate cancer metastases in the lymph nodes and distant lesions. The OSPREY study highlighted the potential of a PSMA-targeted imaging agent to reliably detect metastatic lesions, which could potentially change the course of treatment for these men."

A copy of the presentation can be found on the company's website in the "Events" section.

### **Study Evaluating PyL in Patients with Biochemically Recurrent Prostate Cancer**

Investigators from the Stanford University School of Medicine presented results of their investigator-sponsored trial in a late-breaking abstract titled, "Prospective evaluation of <sup>18</sup>F-DCFPyL in Patients with Biochemically Recurrent Prostate Cancer." PyL was provided for the study under Progenics' PyL Research Access Program.

The study enrolled 50 men with rising PSA after initial treatment with radical prostatectomy or radiation therapy. PSA values ranged from 0.23 to 698 ng/mL, with a mean of 21.6 ng/mL. PyL uptake in multiple areas compatible with prostate cancer showed that PyL imaging localized disease in the majority of patients, including those with very low PSA values. The overall positivity rate in this cohort was 84%.

In addition, PyL imaging had an impact on clinical management in 65% of the patients, including 25% who had negative findings with conventional imaging.

### **About PyL™ for PET Imaging of Prostate Cancer**

PyL (also known as <sup>18</sup>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 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<sup>®</sup>, 1095, and PSMA TTC); prostate-specific membrane antigen ("PSMA") targeted imaging agent for prostate cancer (PyL<sup>™</sup>); 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<sup>®</sup> (methylnaltrexone bromide) for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies Inc.

*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](http://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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