Progenics Pharmaceuticals Reports Top Line Phase 3 Data for Prostate Cancer Imaging Agent 1404

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-Meets Co-Primary Endpoint of Specificity; 1404 Successfully Identifies Patients Without Clinically Significant Prostate Cancer-
-Co-Primary Endpoint of Sensitivity to Identify Patients with Clinically Significant Disease Not Met-

NEW YORK, Sept. 12, 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 top line data from its Phase 3 study of 1404, the Company's prostate specific membrane antigen (PSMA)-targeted small molecule SPECT/CT imaging agent that is designed to visualize prostate cancer.

The Phase 3 trial evaluated the specificity of 1404 imaging to identify patients without clinically significant prostate cancer and sensitivity to identify patients with clinically significant disease. The study dosed 471 patients in the U.S. and Canada with low-grade prostate cancer, whose biopsy indicated a histopathologic Gleason grade of ≤ 3+4 severity and/or were candidates for active surveillance. Median PSA levels for patients dosed in trial was 5.58 ng/mL (range 0.69 – 16.03). In the study, 1404 detected clinically meaningful prostate cancer with specificity ranging among the three readers from 71-75% (95% confidence interval CI of 64% to 80%). The co-primary endpoint of sensitivity was not met and ranged amongst the three readers from 47-51% (95% CI of 41% to 56%). The trial protocol required the lower limit of the two-sided 95% CI for both specificity and sensitivity to exceed 60%.

The most frequent treatment related events included headache (2.3%), dizziness (1.1%) and fatigue (0.8%).

"These top line Phase 3 results of 1404 are inconsistent with the prior Phase 2 data, which showed significantly higher sensitivity rates," stated Mark Baker, CEO of Progenics. "We are currently conducting a thorough analysis of the full data set to understand the factors that may have contributed to this outcome and determine the appropriate development path for this novel agent in patients with low-grade prostate cancer. We plan to complete this review in the next quarter."

Mr. Baker added, "We believe that PSMA-targeted imaging holds tremendous promise to improve the detection, staging and monitoring of prostate cancer. These results do not impact our view of the PyL PET imaging agent in patients with recurrent or metastatic prostate cancer as we head into our Phase 2/3 data readout next quarter, and we remain on track to initiate our second Phase 3 study by year-end. Our oncology therapeutic programs continue to move forward, including the ongoing commercial launch of AZEDRA® for the treatment of pheochromocytoma or paraganglioma. In addition, we anticipate finalizing our clinical development plan with the U.S. FDA for 1095 in metastatic castration-resistant prostate cancer (mCRPC) in the fourth quarter and expect our partner Bayer to initiate a Phase 1 study of PSMA-TTC in patients with mCRPC by year end 2018."

About the Phase 3 1404 Trial

The Phase 3 trial was a multi-center, multi-reader, open-label trial, comparing 1404 SPECT/CT imaging in men who had a diagnostic trans-rectal ultrasound (TRUS) guided biopsy with a histopathologic finding of Gleason score ≤3+4 who were candidates for active surveillance and were undergoing routine biopsy or voluntary radical prostatectomy (RP) with or without a pelvic lymph node dissection. This study was designed to evaluate the sensitivity and specificity of 1404 SPECT/CT image assessments to correctly identify subjects with previously unknown clinically significant prostate cancer in two cohorts: low grade prostate cancer who had elected to undergo RP; and very low risk (VLR) prostate cancer per 2016 National Comprehensive Cancer Network Guidelines who were scheduled to undergo routine prostate biopsy. Subjects received a single dose of 1404 followed by whole body planar and SPECT/CT (pelvic) imaging. In accordance with standard of care procedures, subjects underwent either voluntary RP or prostate biopsy within 42 days after study drug dosing. 1404 image data was collected by a central imaging core laboratory and evaluated for visible uptake within the prostate gland and then compared against central histopathology as the truth standard.

About 1404, an Imaging Compound Targeting Prostate Specific Membrane Antigen

Progenics' molecular imaging radiopharmaceutical product candidate 1404 targets the extracellular domain of prostate specific membrane antigen (PSMA), a protein amplified on the surface of > 95% of prostate cancer cells and a validated target for the detection of primary and metastatic prostate cancer. 1404 is labeled with Technetium-99m, a gamma-emitting isotope that is widely available, is easy to prepare, and is attractive for nuclear medicine imaging applications. The image created provides the opportunity to visualize cancer, potentially allowing for improved detection and staging, more precise biopsies, and a targeted treatment plan including active surveillance as a disease management tool.

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, the cost, timing and unpredictability of results of clinical trials and other development activities and collaborations, such as the Phase 3 clinical program for 1404; market acceptance for approved products; 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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