Progenics Advances 1095, PSMA-Targeted Therapeutic Candidate for the Treatment of Metastatic Prostate Cancer, into Phase 2 Clinical Development Following Discussions with the FDA

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– Trial will utilize PyL imaging in order to target the patients most likely to benefit, advancing the Company's theranostic approach to the treatment of prostate cancer –

NEW YORK, Oct. 11, 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 plans to advance I-131 1095, its PSMA-targeted therapeutic, into a Phase 2 clinical study.

I-131 1095 is a small molecule radiotherapeutic designed to selectively bind to the extracellular domain of prostate specific membrane antigen (PSMA), a protein that is highly expressed on prostate cancer cells. Once 1095 binds to the prostate cancer cells, the drug is internalized and the beta radiation kills the tumor cells. Data from compassionate use of I-131 1095 indicates it was well tolerated and demonstrated markedly reduced PSA levels and bone pain in a group of heavily-pretreated advanced prostate cancer patients following a single cycle of treatment.[1]

"We are pleased, following our discussions with FDA, to move this important therapeutic agent into a phase 2 study in combination with enzalutamide in chemo-naïve patients with mCRPC," stated Vivien Wong, Ph.D., Executive Vice President Development at Progenics. "1095 delivers a targeted radiation dose to prostate cancer cells utilizing iodine-131 as the payload. Iodine 131 is an attractive agent to use because its physical properties of longer range and higher energy could potentially improve efficacy for bulky lesions and lesions that have lower PSMA expression. Iodine has been used widely in other cancer therapeutics, is broadly available with a ready supply and known safety profile. We look forward to evaluating the safety and efficacy of 1095 in this Phase 2 study."

The multicenter, randomized, controlled trial will evaluate the efficacy and safety of 1095 in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC) who are PSMA-avid, chemotherapy naïve, and progressed on abiraterone. 1095 radiotherapy represents a new mechanism of action that may overcome resistance developed to novel androgen axis drugs (NAADs), such as abiraterone and enzalutamide. In addition, recent preclinical research reported that enzalutamide can sensitize cells to radiotherapy induced cell death, suggesting that 1095 in combination with enzalutamide has the potential to be an effective treatment paradigm for patients with mCRPC who are resistant to NAADs.[2]

The study's primary endpoint will be 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 of 1095 and enzalutamide compared to enzalutamide alone. Secondary endpoints will evaluate radiographic response based on Response Evaluation Criteria In Solid Tumors (RECIST), Progression Free Survival (PFS) and overall survival (OS). Tumor avidity will be determined utilizing PyL™ (18F-DCFPyL), the Company's PET imaging agent designed to visualize prostate cancer.

"The design of this trial highlights our differentiated PSMA-targeted theranostic approach which utilizes iodine as the tumor ablator, treats metastatic patients at an earlier stage, is used in combination with enzalutamide, a standard of care NAAD treatment, as well as uses our advanced PyL imaging to select patients most likely to benefit from this treatment," said Mark Baker, CEO of Progenics. "This Phase 2 development program reflects our commitment to developing PSMA-targeted candidates that have the potential to transform how prostate cancer is detected, managed and treated."

Progenics expects to begin enrollment of approximately 120 evaluable patients in the study in early 2019. 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.

About 1095
Progenics' small molecule therapeutic candidate 1095 is designed to bind to the extracellular domain of prostate specific membrane antigen (PSMA), a protein that is highly expressed in prostate cancer cells, and upon binding, to be internalized by the prostate cancer cells, where its iodine-131 beta radiation kills the malignant cell. The ability to specifically deliver radiation to prostate cancer cells anywhere in the body allows a commonly used therapy (radiation) to be used with precision to attack systemic disease. Preclinical data has shown high tumor uptake and a favorable tumor to kidney discrimination yielding a lethal radiation dose to the tumor while minimizing normal tissue dose. In human prostate cancer mouse models, the compound, administered in single or multiple dose schedules, significantly reduced tumor burden for a prolonged period of time and enhanced survival with no significant signs of toxicity. When used in a compassionate use setting, 1095 markedly reduced PSA levels and bone pain in a group of heavily-pretreated advanced prostate cancer patients.

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.

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 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 Phase 2 clinical study for I-131 1095*; 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.

[1]Zechmann et al. Eur J Nucl Med Mol Imaging, 2014
[2]Barrado M et al. bioRxiv, 2018.

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Contact:

Melissa Downs
Investor Relations
(646) 975-2533
mdowns@progenics.com