Progenics Pharmaceuticals Announces Presentation of Updated Data from the Pivotal Trial of AZEDRA® (iobenguane I 131) at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

June 4, 2018

NEW YORK, June 04, 2018 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX), an oncology company developing innovative medicines and other products for targeting and treating cancer, announced updated overall survival data from the Company's pivotal Phase 2 trial of its targeted, high-specific-activity radiotherapeutic candidate, AZEDRA® (iobenguane I 131), in patients with malignant, recurrent, or unresectable pheochromocytoma and paraganglioma (pheo/para), which is the subject of an oral presentation at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois.

"This pivotal study, the largest prospective clinical trial in pheochromocytoma and paraganglioma to date, has demonstrated multiple clinical benefits of AZEDRA treatment, which has translated into impressive overall survival data in this highly pre-treated and advanced patient population," said Dr. Daniel Pryma, Associate Professor of Radiology & Radiation Oncology and Chief, Division of Nuclear Medicine & Clinical Molecular Imaging at the Perelman School of Medicine at the University of Pennsylvania, the trial's lead investigator. "The primary cause of death in pheo/para patients is tumor progression. In this study, 98% of patients who received two doses experienced stable disease or better as measured by Response Evaluation Criteria In Solid Tumors (RECIST). In addition, 30% of pheo/para patients die from complications due to catecholamine-associated hypertension, while patients treated with AZEDRA were able to achieve control of catecholamine-associated hypertension and a sustained reduction of antihypertensive medications. These benefits were correlated with a robust tumor biomarker response. With no approved therapies in the U.S. for pheo and para, AZEDRA has the potential to offer a meaningful treatment option for patients with these life-threatening tumors."

Dr. Pryma will review the data today in an oral presentation entitled, "AZEDRA (iobenguane I 131) in patients with malignant, recurrent and/or unresectable pheochromocytoma or paraganglioma (PPGL): Updated efficacy and safety results from a multi-center, open-label, pivotal phase 2 study."

The pivotal phase 2 open-label, multi-center trial was conducted under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA). The trial met the primary endpoint evaluating the proportion of pheochromocytoma and paraganglioma patients who achieved a 50% or greater reduction of all antihypertensive medication for at least six months, and showed favorable results from a key secondary endpoint evaluating the proportion of patients with overall tumor response as measured by RECIST. 92.2% of patients treated with at least one therapeutic dose of AZEDRA achieved a confirmed partial response or stable disease by 12 months. AZEDRA was also shown to be safe and generally well tolerated.

Median overall survival time as of December 4, 2017 was 37 months from first AZEDRA therapeutic dosing in the overall study population, and 44 months among patients who received two therapeutic doses, compared to 18 months among patients who received only one therapeutic dose. The study data also suggest the potential for AZEDRA to extend survival in patients with liver or lung metastasis, which is generally considered in the literature to be less than 24 months. In this study, median survival time was similar in patients with lung or liver metastasis compared to those without (43 vs. 41 months). Long term follow-up continues.

"These data, which are the basis of our New Drug Application, show that AZEDRA has the potential to address the dual goals of therapy in pheo and para – to reduce the cardiovascular symptoms associated with the excess hormone production, and to produce favorable tumor responses," said Mark Baker, Chief Executive Officer of Progenics. "We are eagerly anticipating the FDA's decision on AZEDRA, as we believe it has the potential to be a breakthrough treatment option for patients with these deadly, ultra-rare neuroendocrine cancers."

About AZEDRA®
AZEDRA (iobenguane I 131) is a high-specific-activity radiotherapeutic product candidate in development as a treatment for malignant, recurrent, or unresectable pheochromocytoma and paraganglioma, which are rare neuroendocrine tumors of neural crest origin. AZEDRA is a substrate for norepinephrine reuptake transporter, which is highly expressed on the cell surface of neuroendocrine tumors. AZEDRA has been granted Orphan Drug designation, Fast Track status, and Breakthrough Therapy designation in the U.S. Under a SPA agreement with the FDA, a Phase 2 pivotal study has been completed in patients with malignant, recurrent, or unresectable pheochromocytoma and paraganglioma. The FDA granted Priority Review of Progenics' New Drug Application and has set an action date of July 30, 2018 under the Prescription Drug User Fee Act. There are currently no FDA-approved therapies for the treatment of these ultra-rare diseases.

About Pheochromocytoma and Paraganglioma
Pheochromocytoma and paraganglioma are rare neuroendocrine tumors that arise from cells of the autonomic nervous system. Pheochromocytoma forms in the adrenal medulla, whereas paragangliomas form outside the adrenal gland. Standard treatment options for these tumors include surgery, palliative therapy and symptom management. Pheochromocytoma and paraganglioma tumors frequently secrete high levels of hormones that can lead to life-threatening hypertension, heart failure, and stroke in these patients. Malignant and recurrent pheochromocytoma and paraganglioma may result in unresectable disease with a poor prognosis, representing a significant management challenge with very limited treatment options and no approved anti-tumor therapies.

About Progenics
Progenics develops innovative medicines and other technologies to target and treat cancer. Progenics' pipeline includes: 1) therapeutic agents designed to precisely target cancer (AZEDRA®, 1095, and PSMA TTC), 2) PSMA-targeted imaging agents for prostate cancer (1404 and PyL™), and 3) imaging analysis technology. Progenics' first commercial product, RELISTOR®(methylnaltrexone bromide) for opioid-induced constipation, is partnered with Valeant Pharmaceuticals International, 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, 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, including our NDA for AZEDRA; market acceptance for approved products; 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 annual period ended December 31, 2017. 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.

(PGNX-F)

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

Primary Logo

Source: Progenics Pharmaceuticals Inc.