Progenics Announces Publication of Pivotal Trial of AZEDRA® (iobenguane I 131) in The Journal of Nuclear Medicine

October 9, 2018

NEW YORK, Oct. 09, 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 that the Company's pivotal trial of AZEDRA® (iobenguane I 131), the Company's radiotherapeutic, has been published in *The Journal of Nuclear Medicine.*

The study entitled, "Efficacy and Safety of High-Specific-Activity I-131 MIBG Therapy in Patients with Advanced Pheochromocytoma or Paraganglioma," reports the complete results of the pivotal study of AZEDRA. This trial was the largest multicenter, prospective trial to evaluate the safety and efficacy of any therapy in patients with pheochromocytoma and paraganglioma and formed the basis of AZEDRA's approval by the U.S. Food and Drug Administration (FDA) in July 2018.

"The successful completion of this pivotal study establishes AZEDRA as a true breakthrough treatment option for patients with pheochromocytoma and paraganglioma, which are deadly, ultra-rare neuroendocrine cancers," 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 and study author. "The primary cause of death in pheo/para patients is tumor progression, while 30% of pheo/para patients die from complications due to catecholamine-associated hypertension. AZEDRA has demonstrated multiple clinical benefits, both reducing tumor size and decreasing the need for blood pressure medication. As the first and only FDA approved therapy for unresectable, locally advanced or metastatic pheo/para requiring systemic anticancer therapy, AZEDRA provides hope for my pheo and para patients and their families."

The pivotal phase 2 open-label, multi-center 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 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. 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.

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.

Approved Use:

AZEDRA® (iobenguane I 131) is a prescription medicine used to treat adult and pediatric patients 12 years and older with cancers known as pheochromocytoma and paraganglioma that are positive for the norepinephrine transporter (as determined by an iobenguane scan), and who require systemic anticancer therapy.

Important Safety Information

AZEDRA can cause serious side effects. If you experience these side effects, your health care provider may need to adjust or stop your treatment. You should always follow your health care provider's instructions. Serious side effects may include:

Radiation exposure: Treatment with AZEDRA will expose you to radiation which can contribute to your overall long-term radiation exposure. Overall radiation exposure is associated with an increased risk for cancer. Radiation risk is greater in children than in adults. You should stay well hydrated before, during, and after your treatment and urinate frequently. Your doctor will advise you on how to lessen exposure to people who may come into contact with you after AZEDRA treatment.

Bone marrow problems and other cancers: Treatment with AZEDRA may cause your blood cell counts to drop (myelosuppression). You may experience blood-related side effects such as low numbers of cells that are responsible for blood clotting (thrombocytopenia), low numbers of a type of white blood cells (neutropenia), and low red blood cells (anemia). Among the 88 patients who received a therapeutic dose of AZEDRA, 33% experienced Grade 4 thrombocytopenia, 16% experienced Grade 4 neutropenia, and 7% experienced Grade 4 anemia. Five percent of patients experienced febrile neutropenia (neutropenia with fever). People with low blood counts can develop serious infections. Your health care provider will routinely check your blood counts and tell you if they are too low. Tell your doctor if you experience any symptoms of low blood counts or infection, such as fever, chills, dizziness, shortness of breath, or increased bleeding or bruising. Your health care provider may need to adjust or stop your treatment accordingly. Other conditions that you may develop as a direct result of treatment with AZEDRA are blood and bone marrow cancers known as secondary myelodysplastic syndrome (MDS) and leukemia. MDS or acute leukemias were reported in 6.8% of the 88 patients who received a therapeutic dose of AZEDRA. The time to development of MDS or acute leukemia ranged from 12 months to 7 years. Two of the 88 patients developed other types of cancer.

Thyroid problems: Treatment with AZEDRA may increase your long-term risk of developing an underactive thyroid (hypothyroidism) or thyroid cancer. Hypothyroidism was reported in 3.4% of the 88 patients who received a therapeutic dose of AZEDRA. Take all thyroid-blocking agents as prescribed by your doctor to reduce the risk of these problems. You may need life-long monitoring for signs and symptoms of hypothyroidism.

Elevations in blood pressure: During or 24 hours following AZEDRA treatment, you may experience increases of blood pressure (hypertension) as a result of hormones released from your cancer. Eleven percent of the 88 patients who received a therapeutic dose of AZEDRA experienced a worsening of pre-existing hypertension. All changes in blood pressure occurred within the first 24 hours after treatment. No life-threatening hypertensive crises have been observed. Monitor blood pressure frequently during the first 24 hours after each therapeutic dose of AZEDRA. Tell your doctor if you experience any cardiac-related symptoms.

Kidney problems: Treatment with AZEDRA will expose your kidneys to radiation and may impair their ability to work as normal. In some cases, patients have experienced kidney failure after treatment with AZEDRA. Of the 88 patients who received a therapeutic dose of AZEDRA, 9% developed kidney failure or acute kidney injury, and 22% experienced a decrease in kidney function measured at 6 or 12 months. Your health care provider will monitor your kidneys after treatment using blood tests, particularly if you already have kidney impairment before treatment.

Respiratory problems: Treatment with AZEDRA may cause noninfectious lung inflammation (pneumonitis). Tell your doctor if you experience shortness of breath, difficulty breathing, or cough.

Pregnancy warning: Before treatment with AZEDRA, tell your doctor if you are pregnant or plan to become pregnant. Exposure to radiation from treatment with AZEDRA can harm your unborn baby. Use an effective method of birth control during treatment with AZEDRA and for 7 months (for females) and 4 months (for males) after your final dose. Do not breastfeed during treatment with AZEDRA and for 80 days after your final dose.

Fertility problems: Treatment with AZEDRA may cause infertility due to radiation absorbed by your testes or ovaries over the treatment period that is within the range of exposure where temporary or permanent infertility may be expected.

The most common and most serious side effects of AZEDRA include decreased blood cell counts, nausea, vomiting and fatigue. These are not all the possible side effects of AZEDRA. For more information, ask your health care provider.

Drugs that reduce catecholamine uptake or that deplete catecholamine stores may interact with AZEDRA and may affect how well it works. These drugs were not permitted in the clinical trials. Tell your doctor before starting any medication, including over the counter medications, herbal or dietary supplements.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information for AZEDRA.

Distributed by: Progenics Pharmaceuticals, Inc., NY 10007

Reference:

AZEDRA® prescribing information. New York, NY: Progenics Pharmaceuticals, Inc.; 08 2018.

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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Contact:

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