Progenics Pharmaceuticals Announces FDA Acceptance of New Drug Application for AZEDRA® (iobenguane I 131) in Pheochromocytoma and Paraganglioma

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NEW YORK, Dec. 29, 2017 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (NASDAQ:PGNX), an oncology company developing innovative medicines and imaging analytical tools for targeting and treating cancer, announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for AZEDRA® in patients with malignant, recurrent and/or unresectable pheochromocytoma and paraganglioma, which are rare neuroendocrine tumors. The FDA granted Progenics’ request for Priority Review and has set an action date of April 30, 2018 under the Prescription Drug User Fee Act (PDUFA).

“With no FDA-approved therapies for these rare tumors, AZEDRA has the potential to address the high unmet need of patients with malignant pheochromocytoma and paraganglioma,” said Mark Baker, Chief Executive Officer of Progenics. “We are pleased that the FDA has accepted our NDA with Priority Review, and look forward to working with the Agency during the review process. At the same time, we will continue to lay the groundwork for our commercial plan and prepare to launch quickly following a potential approval.”

The NDA is supported by data from a pivotal phase 2b open-label, multi-center trial that was conducted under a Special Protocol Assessment (SPA) with the 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 Response Evaluation Criteria In Solid Tumors (RECIST). AZEDRA was also shown to be safe and generally well tolerated.

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 2b pivotal study has been completed in patients with malignant, recurrent, or unresectable pheochromocytoma and paraganglioma. There are currently no FDA-approved therapies for the treatment of this ultra-rare disease.

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® and 1095), 2) PSMA-targeted imaging agents for prostate cancer (1404 and PyL™), and 3) imaging analysis tools. Progenics’ first commercial product, RELISTOR® (methylnaltrexone bromide) for opioid-induced constipation, is partnered with Valeant Pharmaceuticals International, Inc.

This press release may contain 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, such as the Phase 3 clinical program for 1404; our ability to successfully develop and commercialize the products of EXINI Diagnostics AB; the unpredictability of the duration and results of regulatory review of New Drug Applications (NDA) and Investigational NDAs, including our NDA for AZEDRA and related inspections of Progenics’ and its contract manufacturing organizations’ facilities and other sites and other requirements that will need to be met before any approval is obtained; 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017, as updated in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 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. AZEDRA is a registered trademark of Progenics Pharmaceuticals, Inc. Other trademarks are the property of their respective owners.

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