



Progenics Pharmaceuticals Announces Three-Month Extension of PDUFA Date for AZEDRA® (iobenguane I 131)

March 22, 2018

NEW YORK, March 22, 2018 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX), an oncology company developing innovative medicines and imaging analysis technology for targeting and treating cancer, announced today that the Company has received notification from the U.S. Food and Drug Administration (FDA) that the Agency will extend its review of the New Drug Application (NDA) for AZEDRA® (iobenguane I 131) by three months to July 30, 2018.

The extension is the result of the submission of additional Chemistry, Manufacturing, and Controls (CMC) information by Progenics, which required additional time for FDA review. The standard three-month extension is not related to the efficacy or safety data of AZEDRA.

"We remain confident in our NDA submission and are committed to bringing AZEDRA forward as an option for patients with malignant pheo and para," said Mark Baker, Chief Executive Officer of Progenics. "We look forward to continuing our dialogue with the Agency as we prepare for a potential approval of AZEDRA."

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 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; 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.

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