# Aktis Oncology Receives U.S. FDA Fast Track Designation for AKY-1189, a Nectin-4 Miniprotein Radioconjugate

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- U.S. FDA Fast Track designation granted to AKY-1189[1] for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have progressed on or after prior systemic therapies
- Ongoing Phase 1b trial of AKY-1189 enrolling patients with locally advanced or metastatic urothelial cancer and several other Nectin-4 expressing tumor types

BOSTON, Feb. 24, 2026 (GLOBE NEWSWIRE) -- Aktis Oncology, Inc. (NASDAQ:AKTS), a clinical-stage oncology company focused on expanding the breakthrough potential of targeted radiopharmaceuticals to large patient populations, including those not addressed by existing platform technologies, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to AKY-1189 for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have progressed on or after prior systemic therapies. Generated using Aktis' miniprotein radioconjugate platform, AKY-1189 is designed to deliver actinium-225 ($^{225}$Ac), a highly potent alpha-emitting radioisotope, to Nectin-4 expressing tumors. Approximately 80 – 90% of urothelial cancer patients show positive expression of Nectin-4.

Fast Track designation is an FDA process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to bring important new drugs to patients earlier. A drug that receives Fast Track designation may be eligible for more frequent interactions and communications with the FDA and the ability to submit a Biologics License Application on a rolling basis.

"Patients with locally advanced or metastatic urothelial cancer who progress on systemic therapies, such as PADCEV, have limited treatment options," said Akos Czibere, MD, PhD, Chief Medical Officer of Aktis Oncology. "The granting of Fast Track designation affords us a unique opportunity to work closely with the FDA to potentially expedite the development and review process of AKY-1189 with the goal of addressing this unmet medical need by bringing a new therapeutic option to patients with locally advanced or metastatic urothelial cancer."

Aktis is currently conducting a multi-site Phase 1b clinical trial (NCT07020117) of AKY-1189 in the United States for the treatment of locally advanced or mUC, breast cancer, non-small cell lung cancer, colorectal cancer, cervical cancer, and head and neck cancer. Aktis expects to present preliminary results from Part 1 of the trial in the first quarter of 2027.

**About Aktis' Radioconjugate Platform**
Aktis has developed a proprietary, isotope-agnostic miniprotein radioconjugate platform to selectively deliver the tumor-killing properties of radioisotopes to targeted tumors. Aktis' therapeutic miniprotein radioconjugates are designed to maximize anti-cancer activity through high penetration, internalization and retention in cancer cells, while quickly clearing from normal organs and tissues. The Aktis platform further enables clinicians to visualize and verify target engagement with imaging isotopes prior to exposure to therapeutic radioisotopes. Leveraging this platform, Aktis is advancing a pipeline of next-generation targeted radiopharmaceuticals to address the unmet needs of patients across a broad spectrum of solid tumors.

**About Aktis Oncology**
Aktis Oncology, Inc. is a clinical-stage oncology company focused on expanding the breakthrough potential of targeted radiopharmaceuticals to large patient populations, including those not addressed by existing platform technologies. Aktis' most advanced pipeline program, AKY-1189, is a miniprotein radioconjugate targeting Nectin-4, with multi-indication potential across multiple tumor types, including locally advanced or metastatic urothelial cancer, breast cancer, non-small cell lung cancer, colorectal cancer, cervical cancer, and head and neck cancer. Aktis' second pipeline program, AKY-2519, is a miniprotein radioconjugate targeting B7-H3 expressing tumors, including prostate, lung and other solid tumors. Aktis has a strategic collaboration with Eli Lilly and Company to leverage its miniprotein platform to develop novel radioconjugates outside of Aktis' proprietary pipeline.

**Forward-Looking Statements**
This communication contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and other federal securities laws. Any statements contained herein which do not describe historical facts should be considered forward-looking statements, including, among others, the potential of AKY-1189 to treat locally advanced or metastatic urothelial cancer and other Nectin-4 expressing tumors, the anticipated timing of the Part 1 data from Aktis' on-going Phase 1b clinical trial, the potential benefits conferred by Fast Track designation for AKY-1189; and Aktis' plans with respect to the development of its product candidates, including AKY-1189.

Forward-looking statements are based on management's current beliefs and assumptions, which are subject to risks and uncertainties and are not guarantees of future performance. Such risks and uncertainties include, among others, the timing, scope, progress and results of Aktis' research and development programs, preclinical studies, clinical trials, investigational new drug or biological license applications, and other regulatory submissions; the timing of, and costs involved in, obtaining and maintaining regulatory approval of AKY-1189 for locally advanced or metastatic urothelial cancer and other Nectin-4 expressing tumors, Aktis' other product candidates, or any future product candidates that it may identify or develop; the ability to obtain an adequate supply at reasonable costs of $^{225}$Ac or any other radioisotope it may incorporate into its drug candidates; estimates regarding the market opportunities for Aktis' drug candidates; Aktis' intellectual property position, including the scope of protection it is able to establish, maintain, defend, protect and enforce for intellectual property rights covering its product candidates; the accuracy of Aktis' estimates regarding future expenses, future revenue, capital requirements and need for additional financing; Aktis' financial performance and its ability to effectively manage its anticipated growth; and such other risks and uncertainties identified in Aktis' periodic, current and other filings with the Securities and Exchange Commission (SEC), including its final prospectus filed with the SEC on January 9, 2026 and any subsequent filings with the SEC, which are available at the SEC's website at www.sec.gov. Any such risks and uncertainties could materially and adversely affect Aktis' results of operations and its cash flows, which would, in turn, have a significant and adverse impact on Aktis' stock price. Aktis cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Aktis disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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[1] AKY-1189 refers to the therapeutic radioconjugate [$^{225}$Ac]Ac-AKY-1189.