Aktis Oncology Initiates Phase 1b Clinical Trial for AKY-2519, a B7-H3 Miniprotein Radioconjugate, in Metastatic Castration-Resistant Prostate Cancer (mCRPC)

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- Clinical development strategy includes an mCRPC-dedicated Phase 1b trial in PLUVICTO®-naïve and -experienced patients, and a second Phase 1b basket trial in other B7-H3 expressing solid tumors
- Two-trial strategy enables evaluation of AKY-2519 in broader patient segments and efficient generation of indication-relevant data; preliminary mCRPC data expected in 2027
- Aktis to hold conference call tomorrow, Tuesday, May 5, 2026, at 8 a.m. ET to discuss its clinical development strategy for AKY-2519

BOSTON, May 04, 2026 (GLOBE NEWSWIRE) -- Aktis Oncology, Inc. (NASDAQ:AKTS) (Aktis or the Company), a clinical-stage oncology company focused on expanding the breakthrough potential of targeted radiopharmaceuticals to large populations, today announced the initiation of a Phase 1b clinical trial of AKY-2519[1] in patients with metastatic castration-resistant prostate cancer (mCRPC). The mCRPC-dedicated Phase 1b trial is part of Aktis' clinical development strategy to develop AKY-2519 broadly in B7-H3 expressing tumors. Aktis plans to initiate a Phase 1b basket trial in lung, colorectal, and other high B7-H3 expressing solid tumors in the second half of 2026.

"We see an opportunity to advance broad clinical development of AKY-2519 given the high expression of B7-H3 across multiple solid tumor types and associated poor prognosis. We are excited to advance a two-trial strategy, which enables us to evaluate AKY-2519 broadly in multiple patient subsets and to efficiently generate indication-relevant data for actionable, data-driven decision-making," said Akos Czibere, MD, PhD, Chief Medical Officer at Aktis. "This strategy was informed by insights from our clinical advisory boards and reflects the distinct treatment patterns and clinical needs of patients with mCRPC compared to other solid tumor patients. Importantly, this allows us to generate data in mCRPC in both PLUVICTO®-naïve and -experienced patients to maximize the potential impact of AKY-2519."

"Prostate cancer is one of the most important indications for therapeutic radiopharmaceuticals; however, many unmet needs persist," said Oliver Sartor, MD, LCMC Health, Director, Transformational Prostate Cancer Research Center, New Orleans, LA. "A substantial number of mCRPC patients are ineligible for PSMA-targeted therapy due to low target expression and even more importantly, many patients have a sub-optimal response to PSMA targeted therapy. We all agree that further improvements are needed. Given high expression in mCRPC, B7-H3 represents a promising new target. The Phase 1b mCRPC AKY-2519 clinical study is a critical step in learning more about the safety and efficacy of a promising new next-generation B7-H3 targeted radiopharmaceutical. We look forward to learning more from these investigations."

The first Phase 1b open label trial will enroll patients with mCRPC, including both PLUVICTO-naïve and PLUVICTO-experienced cohorts, at multiple prostate-specific radioligand therapy centers in the U.S. The study will explore three dose levels in each cohort. Following dose escalation, the trial will expand enrollment at selected dose levels to generate additional clinical data. Preliminary data are expected in 2027. The second Phase 1b multi-center, open label trial will enroll patients in the U.S. with lung, colorectal, and other high B7-H3 expressing solid tumors. The protocol for this basket trial has been finalized and is currently under regulatory review.

AKY-2519 is the second miniprotein Aktis has advanced to the clinic in the past 12 months. Aktis' lead program, AKY-1189, a miniprotein radioconjugate protein targeting Nectin-4 expressing tumors, is currently enrolling patients in an ongoing Phase 1b trial, with preliminary data anticipated in the first quarter of 2027.

Conference Call and Webcast Information
Aktis will host a live conference call and webcast tomorrow, Tuesday, May 5, 2026, at 8 a.m. ET to discuss its clinical development strategy for AKY-2519. To access the conference call, please register here. Registrants will receive the dial-in number and unique PIN. A live webcast of the call will be available under "Events" in the Investors section of the Aktis Oncology website at investors.aktisoncology.com. The archived webcast will be available for 90 days following the call.

PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan) is a registered trademark of Novartis Pharmaceuticals Corporation.

About Aktis' miniprotein 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 tumor penetration coupled with internalization and retention in cancer cells, while rapidly 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, and its patient-first end-to-end supply chain, 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 clinical-stage 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 clinical-stage pipeline program, AKY-2519, is a miniprotein radioconjugate targeting B7-H3 expressing tumors, including prostate, lung, colorectal, and other solid tumors. Aktis has a discovery collaboration with Eli Lilly and Company to leverage Aktis' miniprotein platform to develop novel radioconjugates outside of its proprietary pipeline. For more information, please visit www.aktisoncology.com.

Forward-looking statements
This press release contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the Company's expectations about the timing of ongoing and planned clinical trials and regulatory filings, goals to develop and commercialize its product candidates, its liquidity and capital resources, and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond the Company's control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to the timing of enrollment, commencement and completion of the Company's ongoing and planned clinical trials, the Company's limited operating history, its ability to obtain necessary funding, its ability to generate positive clinical trial results for its product candidates and other risks inherent in clinical development, the timing and scope of regulatory approvals, changes in laws and regulations to which the Company is subject, competitive pressures, risks relating to business interruptions, and other risks set forth under the heading "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2025 and in subsequent filings with the Securities and Exchange Commission. The Company's actual results could differ materially from the results described in or implied by such forward looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, the Company undertakes no obligation to update or revise these forward-looking statements.

Media contact:
Melone Communications, LLC
Liz Melone
617-256-6622
liz@melonecomm.com

Investor contact:
Precision AQ
Alex Lobo
212-698-8802
Alex.lobo@precisionaq.com

[1]AKY-2519 refers to the therapeutic radioconjugate [^{225}Ac]Ac-AKY-2519.