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Aktis Oncology Initiates Second Phase 1b Clinical Trial for AKY-2519, a Miniprotein Radioconjugate Targeting B7-H3

- Phase 1b BActinium-2 clinical trial is evaluating AKY-2519 in patients with non-small cell lung cancer (NSCLC) and other B7-H3 expressing tumors
- Enrollment is ongoing in the Phase 1b BActinium-1 clinical trial of AKY-2519 in metastatic castration-resistant prostate cancer (mCRPC); preliminary data expected in 2027

BOSTON, Oct. 01, 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 the Phase 1b BActinium-2 trial of AKY-2519¹ in patients with NSCLC and other B7-H3 expressing solid tumor types. The BActinium-2 trial is part of Aktis' clinical development strategy to develop AKY-2519 broadly in several B7-H3 expressing tumors. In May 2026, Aktis initiated the Phase 1b BActinium-1 trial of AKY-2519 in mCRPC patients, with preliminary data expected in 2027.

"AKY-2519 has the potential to be a differentiated therapeutic option for patients with B7-H3 expressing solid tumors, as demonstrated by the first-in-human clinical imaging and dosimetry data presented at ASCO earlier this year," said Akos Czibere, MD, PhD, Chief Medical Officer at Aktis. "With both Phase 1b trials of AKY-2519 now underway, we are efficiently generating indication-relevant data in several cancers with large patient populations to evaluate where AKY-2519 can be most effective."

The first-in-human clinical imaging and dosimetry data for AKY-2519 across mCRPC, NSCLC and other B7-H3 expressing tumor types presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in May 2026 demonstrated robust tumor uptake and retention of AKY-2519 with limited normal tissue exposure, suggesting the potential for a wide therapeutic window and differentiated profile compared to approved radiopharmaceuticals.

The Phase 1b, multicenter, open-label BActinium-2 trial will enroll patients with NSCLC and other B7-H3 expressing solid tumors. The study will explore three dose levels. Per protocol, Aktis has the

ability to expand enrollment at selected dose levels to generate additional clinical data while dose escalation continues.

In addition to the AKY-2519 BActinium-1 and BActinium-2 trials, Aktis is also currently enrolling patients in an ongoing Phase 1b NECTINIUM-2 trial of its most advanced program, AKY-1189, a miniprotein radioconjugate targeting Nectin-4 expressing tumors, with preliminary data expected in the first quarter of 2027.

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 anticancer 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 clinical supply chain built for resiliency and scalability, 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, and other solid tumor cancers. Aktis' second clinical-stage pipeline program, AKY-2519, is a miniprotein radioconjugate targeting B7-H3 expressing tumors, including prostate, lung, 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 and results of ongoing and planned clinical trials and regulatory filings, goals to develop and commercialize its product candidates, 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 commencement and completion of the Company's ongoing and planned clinical trials, the Company's limited operating history, 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 30, 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.

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