Aktis Oncology Announces FDA Clearance of Investigational New Drug Applications for AKY-2519 and Provides Business Updates and Full Year 2025 Financial Results

03/30/2026

- Progressing vision to expand the reach of targeted radiopharmaceuticals to large patient populations
- Anticipating multiple milestones in the next 12 months, including initiation of Phase 1b clinical trial of AKY-2519 in mid-2026

BOSTON, March 30, 2026 (GLOBE NEWSWIRE) -- Aktis Oncology, Inc. (NASDAQ:AKTS) (the "Company"), a clinical-stage oncology company focused on expanding the breakthrough potential of targeted radiopharmaceuticals to large populations, including those not addressed by existing platform technologies, today announced the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) applications for the Company to proceed to a Phase 1b clinical trial with AKY-2519[1]. AKY-2519 is a miniprotein radioconjugate targeting B7-H3, which is expressed in several solid tumor types including prostate and lung cancers, and is the second clinical stage miniprotein radioconjugate discovered using Aktis' proprietary platform. The Company's lead miniprotein radioconjugate, AKY-1189, targeting Nectin-4, is currently enrolling patients in a Phase 1b clinical study. Aktis' miniprotein radioconjugates are designed to selectively deliver actinium-225 (^{225}Ac), a highly potent alpha-emitting radioisotope, to target-expressing tumors. The Company also provided business updates and reported financial results for the year ended December 31, 2025.

"Aktis was founded to improve outcomes for cancer patients by pioneering a new class of targeted radiopharmaceuticals for prevalent tumor types that have historically been beyond the reach of this modality," said Matthew Roden, Ph.D., President and Chief Executive Officer of Aktis Oncology. "We continue to make significant progress on all fronts of our plan, including advancing the enrollment of our Phase 1b clinical trial of AKY-1189 in patients with Nectin-4 expressing tumors, which was granted FDA Fast Track designation in February, as well as the recent clearance of our IND applications for AKY-2519. We are excited to accelerate the AKY-2519 program to patients in need of improved treatment options, and now expect to commence a Phase 1b trial of AKY-2519 in mid-2026. This momentum, together with our proprietary miniprotein radioconjugate platform, supply chain infrastructure, and strong cash position, strengthens our leadership in targeted radiopharmaceuticals."

Dr. Roden continued, "AKY-1189 and AKY-2519 each represent significant patient impact opportunities, with the potential to address multiple indications across various tumor types. We are working urgently to generate the clinical data necessary to support registrational trials for both programs."

Business updates and anticipated key milestones

Pipeline

AKY-1189, a novel miniprotein radioconjugate designed to selectively deliver ^{225}Ac to Nectin-4 expressing tumors, is in an ongoing Phase 1b clinical trial enrolling patients with locally advanced or metastatic urothelial cancer (mUC), breast cancer, non-small cell lung cancer, colorectal cancer, cervical cancer, and head and neck cancer.

In February 2026, the FDA granted Fast Track designation for AKY-1189 for the treatment of adult patients with locally advanced or mUC who have progressed on or after prior systemic therapies.

AKY-2519, a miniprotein radioconjugate designed to selectively deliver ^{225}Ac to B7-H3 expressing tumors, including prostate, lung and other solid tumors, is in an ongoing imaging and dosimetry clinical assessment of AKY-2519 to enable initial understanding of biodistribution and uptake in tumors and normal tissues.

In March 2026, the FDA cleared the IND applications for [^{64}Cu]Cu-AKY-2519 (imaging) and [^{225}Ac]Ac-AKY-2519 (therapeutic use) to proceed to a Phase 1b clinical trial.

Corporate

On January 8, 2026, the Company priced an initial public offering (IPO) of its common stock, raising $365.4M gross proceeds, before underwriting discounts and other offering-related expenses.

Anticipated key milestones for the next 12 months

- AKY-1189: Preliminary data from Part 1 of the ongoing Phase 1b clinical trial are expected in the first quarter of 2027.
- AKY-2519:

    - Results from clinical imaging and dosimetry assessment of AKY-2519 in patients with various solid tumors are expected in mid-2026.
    - Phase 1b clinical trial is expected to commence in mid-2026. The Company plans to provide further details on the overall clinical development strategy of AKY-2519 at that time.
- Early pipeline: Two programs are tracking toward development candidate nomination and commencement of IND-enabling activities in the first quarter of 2027.
- Corporate: In-house Good Manufacturing Practices (GMP) facility is expected to be operational in the second half of 2026 as part of the Company's hybrid manufacturing strategy to expand capabilities and support clinical supply demand.

2025 financial results

- **Cash position:** Cash, cash equivalents and marketable securities were $226.8 million as of December 31, 2025, compared to $297.2 million as of December 31, 2024. Subsequent to December 31, 2025, the Company completed its IPO, generating net proceeds of approximately $335.3 million, after underwriting discounts, commissions and offering-related expenses. As a result, the Company's pro forma as adjusted cash position as of year-end 2025 was $562.1 million, reflecting cash, cash equivalents and marketable securities as of December 31, 2025, plus net proceeds from the January 2026 IPO. The Company believes that the pro forma as adjusted cash position will fund its operations into 2029.
- **Collaboration revenue:** Collaboration revenue was $6.5 million for the year ended December 31, 2025, compared to $1.5 million for the year ended December 31, 2024. The increase was attributable to revenue recognized under the Company's collaboration with Eli Lilly and Company, which was entered into in May 2024. In 2024, revenue recognition began in the fourth quarter, whereas a full year of revenue was recognized in 2025.
- **R&D expenses:** Research and development expenses were $67.5 million for the year ended December 31, 2025, compared to $41.0 million for the year ended December 31, 2024. The increase was primarily driven by higher headcount, and increased program expenses to support the advancement of AKY-1189 in a Phase 1b clinical trial and AKY-2519 IND-enabling studies and clinical imaging and dosimetry assessment.
- **G&A expenses:** General and administrative expenses were $13.7 million for the year ended December 31, 2025, compared to $12.6 million for the year ended December 31, 2024. The increase was primarily due to higher headcount to support the Company's growing business.
- **Net loss:** Net loss was $63.7 million for the year ended December 31, 2025, compared to $44.0 million for the year ended December 31, 2024. The increase in net loss was primarily driven by the increase in R&D expenses described above.

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, 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. 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 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, its ability to identify additional product candidates, 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.

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[1] IND applications were cleared for [^{64}Cu]Cu-AKY-2519 for imaging and [^{225}Ac]Ac-AKY-2519 for therapeutic use.