Aktis Oncology Reports First-in-Human Clinical Imaging and Dosimetry Data for AKY-2519 Demonstrating Robust Tumor Uptake and Limited Normal Tissue Exposures in Patients with B7-H3 Expressing Tumors

05/21/2026

- Data to be presented across two posters at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting
- Combined results evaluating AKY-2519 across several B7-H3 expressing tumor types, including metastatic castration-resistant prostate cancer (mCRPC), suggest a potentially differentiated profile compared to approved radiopharmaceuticals
- Aktis to hold conference call on Wednesday, May 27, 2026, at 8:00 a.m. ET with leading clinical investigators, Oliver Sartor, M.D., and Timothy Yap, MBBS, Ph.D., to discuss results

BOSTON, May 21, 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, including those not addressed by existing platform technologies, today reported first-in-human clinical imaging and dosimetry data for AKY-2519, a miniprotein radioconjugate targeting B7-H3 expressing tumors. The data from two separate assessments of AKY-2519 – a clinical imaging and dosimetry assessment in patients with mCRPC and a clinical imaging assessment in patients with various solid tumor types – demonstrated robust tumor uptake and limited normal tissue exposure. These findings, which supported the advancement of a broad clinical development program for AKY-2519, will be presented in two poster presentations at the upcoming 2026 ASCO Annual Meeting, being held May 29 – June 2, 2026, in Chicago.

“We’re excited to report the first clinical imaging and dosimetry data for AKY-2519, which offer a potentially differentiated therapeutic option for patients with B7-H3 expressing tumors, including mCRPC, lung cancer, and colorectal cancer, among others,” said Matthew Roden, Ph.D., President and Chief Executive Officer at Aktis. “These data informed the design of our ongoing Phase 1b clinical trial in patients with mCRPC and a second Phase 1b trial of AKY-2519 in various B7-H3 expressing tumor types, which we expect to initiate in the second half of this year. The broad development opportunity for AKY-2519, our second clinical-stage program for multiple tumor types, exemplifies our vision to bring targeted radiopharmaceuticals to large patient populations with significant unmet need.”

Akos Czibere, M.D., Ph.D., Chief Medical Officer at Aktis commented, “These first-in-human clinical imaging and dosimetry data suggest the potential of AKY-2519 to expand targeted radiopharmaceuticals to broader patient populations while also offering a potentially important new radiopharmaceutical option for the mCRPC patient population. The robust tumor uptake and retention and low normal tissue uptake consistently seen with AKY-2519 in these assessments gives us an initial understanding of its potential to kill cancer cells while minimizing normal-tissue radiation exposure. Moreover, the low predicted dose in salivary glands suggests AKY-2519’s unique potential as a B7-H3-targeted agent for mCRPC versus PSMA-targeting agents.”

B7-H3 is highly expressed in mCRPC, lung, colorectal and various other solid tumor types, with limited expression in normal tissues. High tumor expression of B7-H3 has been shown to be associated with poor prognosis and lack of response to certain therapies in multiple tumor types. AKY-2519 is the second clinical-stage targeted miniprotein radioconjugate discovered and developed from Aktis’ proprietary platform. The program includes [^{64}Cu]Cu-AKY-2519 for imaging with copper-64 (^{64}Cu) and [^{225}Ac]Ac-AKY-2519 for therapeutic use with actinium-225 (^{225}Ac).

Aktis is currently enrolling patients in an mCRPC-dedicated Phase 1b trial of AKY-2519 in PLUVICTO®-naïve and PLUVICTO®-experienced patients, with preliminary data anticipated in 2027. The Company is on track to initiate a second Phase 1b trial of AKY-2519 in other B7-H3 expressing solid tumors in the second half of 2026. Aktis’ lead program, AKY-1189, a miniprotein radioconjugate targeting Nectin-4 expressing tumors, is currently being evaluated in a Phase 1b trial, with preliminary data expected in the first quarter of 2027.

About the AKY-2519 ASCO data presentations

Poster title: AKY-2519, a novel B7-H3–targeted radioconjugate, demonstrates a differentiated biodistribution profile with low normal tissue exposure and robust tumor doses in patients with mCRPC
Poster #: 234 / **Abstract #:** 3097 **/ Date & Time:** Saturday, May 30, 1:30 – 4:30 p.m. CDT

Assessment background and methods

Conducted at the Nuclear Medicine Research Infrastructure (NuMeRI) at the University of Pretoria and Steve Biko Academic Hospital, South Africa, the assessment evaluated the biodistribution and dosimetry of AKY-2519, using [^{68}Ga]Ga-AKY-2519 and

low dose, non-therapeutic [^{177}Lu]Lu-AKY-2519 as imaging surrogates in 16 patients with mCRPC. In the first part of the assessment, patients were given [^{68}Ga]Ga-AKY-2519 and imaged using PET/CT at 30, 60, and 90 - 150 minutes to evaluate normal tissue distribution, tumor uptake and comparison with uptake of FDA-approved diagnostic PSMA-11. In the second part of the imaging assessment, patients were given low-dose, non-therapeutic [^{177}Lu]Lu-AKY-2519 and imaged using SPECT/CT at 3, 24, and 144 hours to evaluate dosimetry (mean absorbed dose) and to estimate predicted [^{225}Ac]Ac-AKY-2519 absorbed doses, at a therapeutic administration schedule of 8 MBq x4, in normal tissues and tumors.

Data highlights

Safety and tolerability

- Administration of AKY-2519 was generally well tolerated, with no adverse events or infusion-related reactions reported with either [^{68}Ga]Ga-AKY-2519 or [^{177}Lu]Lu-AKY-2519.

Imaging and dosimetry results

- Predicted absorbed doses of AKY-2519 in key normal tissues (bone marrow, liver, kidneys, salivary glands) were estimated to be favorable when compared to reference clinical benchmarks.
- Notably, the predicted absorbed dose of AKY-2519 to the salivary glands was lower compared to approved radiopharmaceuticals.

Table 1. Predicted [^{225}Ac]Ac-AKY-2519 absorbed doses in critical normal tissues

Normal Tissue (n=12)[a]	Mean Absorbed Dose Coefficient (^{225}Ac) $Gy_{RBE=5}$/MBq(SD)	Predicted Absorbed Dose at 8 MBq x 4 Gy_{RBE}=5
Bone marrow	0.04 (0.02)	1.3
Liver	0.31 (0.10)	9.9
Kidneys	0.50 (0.17)	16
Salivary glands	0.13 (0.04)	4.2

[a][^{177}Lu]Lu-AKY-2519 was used as a surrogate for estimation of absorbed doses with [^{225}Ac]Ac-AKY-2519. Of the 16 patients with [^{177}Lu]Lu-AKY-2519 dosimetry data available, 12 had sufficient data for conversion to [^{225}Ac]Ac-AKY-2519; RBE, relative biological effectiveness; SD, standard deviation.

- AKY-2519 demonstrated robust tumor uptake and retention in tumors for at least 6 days after administration.
- Predicted absorbed doses of AKY-2519 to prospectively selected tumors, including involved prostate and seminal vesicles and nodal and bony metastases, were within expected therapeutic ranges for approved radiopharmaceuticals.
- The combined findings of predicted absorbed doses in tumors and normal tissues suggest a wide therapeutic index and a favorable profile for AKY-2519 compared to approved radiopharmaceuticals.

Table 2. Estimated tumor absorbed doses of [225Ac]Ac-AKY-2519 in mCRPC lesions

Lesion Location	Evaluable Patients	Mean Absorbed Dose Coefficient[a](^{225}Ac) $Gy_{RBE=5}$/MBq(SD)	Mean Absorbed Dose Coefficient with PVC (^{225}Ac) $Gy_{RBE=5}$/MBq(SD)	Predicted Absorbed Dose at 8 MBq x 4 Gy_{RBE}=5	Predicted Absorbed Dose[b]at 8 MBq x 4 with PVC Gy_{RBE}=5
Involved prostate ± seminal vesicles	8	2.6 (1.2)	N/A[c]	83 (39)	N/A[c]
Nodal metastases	5	4.4 (2.8)	8.4 (4.2)	141 (88)	268 (134)
Bony metastases	6	1.5 (0.8)	3.8 (1.8)	48 (25)	121 (57)

[a]Where multiple regions of interest (ROIs) of the same category were available in a single patient (nodal or bony metastasis), the highest value was utilized. [b]Projected absorbed dose estimates are calculated based on the corresponding raw dose coefficient for the ROI. [c]Partial volume correction (PVC) was not applied for ROI analysis of involved prostate due to spillover activity from adjacent bladder. SD, standard deviation

AKY-2519 and PSMA-11 comparison

- Distribution of tumor uptake appears comparable between [^{68}Ga]Ga-AKY-2519 and [^{68}Ga]Ga-PSMA-11 at the standard 60 minutes measurement time point, with tumor uptake with [^{68}Ga]Ga-AKY-2519 increasing over time.

Poster Presentation 2: First-in-Human PET/CT imaging with [69Ga]Ga-AKY-2519, a B7-H3 Targeted Miniprotein Conjugate, to demonstrate tumor uptake and normal tissue exposure across various advanced solid tumors
Poster #: 235 / **Abstract #:** 3098 / **Date & Time:** Saturday, May 30, 1:30 – 4:30 p.m. CDT

Assessment background and methods

Conducted by the Department of Nuclear Medicine, University of Duisburg-Essen and German Cancer Consortium (DKTK), Universitätsklinikum Essen (University Hospital Essen), Essen, Germany, the assessment evaluated the biodistribution and tumor uptake of [^{68}Ga]Ga-AKY-2519 in patients with advanced or metastatic disease in a variety of solid tumors, including prostate, lung, colorectal, and other tumor types (n=18). Following intravenous administration of [^{68}Ga]Ga-AKY-2519 patients were imaged with PET/CT and SUV (standardized uptake value) measurements were taken to assess tumor uptake and normal tissue distribution at 15, 60 and 120 minutes.

Data highlights

Safety and tolerability

- Administration of [^{68}Ga]Ga-AKY-2519 was generally well tolerated, with no adverse events or infusion-related reactions reported.

Imaging results

- Robust uptake of [^{68}Ga]Ga-AKY-2519 as measured by SUV_{max} was observed across multiple tumor types, including prostate, non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), and rectal cancer at various time points out to 120 minutes with representative patients showing:
  - Prostate cancer: SUV_{max} = 33.9-37.4;
  - NSCLC: SUV_{max} = 17.5-21.5;
  - SCLC: SUV_{max} = 15.4; and
  - Rectal cancer: SUV_{max} = 15.3.
- In prostate cancer, high [^{68}Ga]Ga-AKY-2519 tumor uptake was consistently observed across metastatic disease sites with the most intense uptake observed in bone and visceral metastases.

Table 3. Uptake of [^{68}Ga]Ga-AKY-2519 (120 min post infusion) in multiple metastatic disease sites from patients with prostate cancer (n=7)

	Bone Metastases	Lymph Node Metastases	Visceral Metastases
Median SUV_{max}	40.4	13.8	31.0
Median SUV_{peak}	25.0	6.5	22.2
Median SUV_{mean}	16.1	5.1	18.7

SUV, standard uptake value

- PET/CT imaging 120 min after [^{68}Ga]Ga-AKY-2519 injection showed low uptake in critical normal tissues.

Table 4. Uptake of [^{68}Ga]Ga-AKY-2519 (120 min post infusion) in normal tissues of patients with solid tumors (n=18)

	Adrenal Glands	Bone Marrow	Kidneys	Liver	Salivary Glands	Spleen
Median (IQR) SUV_{max}	17.5 (15.9—19.8)	4.1 (3.3—5.1)	6.7 (6.3—8.7)	22.9 (20.9—30.8)	7.3 (6.4—11.4)	9.2 (7.6—10.4)

Conference call and webcast information
Aktis will host a live conference call and webcast on Wednesday, May 27, 2026, at 8 a.m. ET to discuss the AKY-2519 imaging and dosimetry data with leading clinical investigators, Oliver Sartor, M.D., LCMC Health, Director, Transformational Prostate Cancer Research Center (New Orleans, LA), and Timothy A. Yap, MBBS, Ph.D., Vice President and Head of Clinical Development, Therapeutics Discovery Division; Professor, Department of Investigational Cancer Therapeutics (Phase I Program), University of Texas MD Anderson Cancer Center. 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 also 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.

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 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 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.

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