

AKTIS ONCOLOGY ANNOUNCES  
PRESENTATION OF THE FIRST  
CLINICAL DATA SUPPORTING BROAD  
DEVELOPMENT OF A FIRST IN CLASS  
NECTIN-4 TARGETING  
RADIOPHARMACEUTICAL AKY-1189  
AT 2024 EORTC-NCI-AACR  
SYMPOSIUM ON MOLECULAR  
TARGETS AND CANCER  
THERAPEUTICS



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**Aktis Oncology** →

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*AKY-1189 is a novel Nectin-4 targeted radiopharmaceutical product candidate demonstrating substantial tumor uptake across several solid tumor types and is progressing in human development as a therapeutic agent*

*AKY-1189 was engineered to deliver actinium-225 directly to tumors while minimizing exposure to normal organs and tissues*

BOSTON, Oct. 24, 2024 /PRNewswire/ -- **Aktis Oncology**, a clinical-stage oncology company focused on unlocking the breakthrough potential of targeted radiopharmaceuticals for large patient populations not addressed by existing platform technologies, today announced data presented on its potential first-in-class, Nectin-4 targeting miniprotein radiopharmaceutical, AKY-1189, in three abstracts, including one oral presentation, at the **EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics** in Barcelona, Spain, October 23-25, 2024. AKY-1189 is designed to deliver actinium-225 to Nectin-4 expressing tumors, with potential applications in locally advanced or metastatic urothelial carcinoma (mUC) and other Nectin-4 expressing cancers, such as breast, lung, colorectal and cervical.

Mike Sathekge, MD, Head of Nuclear Medicine Department, University of Pretoria, and Steve Biko Academic Hospital, and President and CEO, Nuclear Medicine Research Infrastructure (NuMeRI), will present an oral plenary on the human biodistribution and dosimetry data of AKY-1189. The plenary presentation (**Abstract no. 10**), titled "**AKY-1189, a novel, first-in-class miniprotein radiopharmaceutical designed to deliver Actinium-225 (225Ac) to Nectin-4 expressing tumors with broad therapeutic applications in metastatic urothelial carcinoma (mUC) and other Nectin-4 expressing tumors,**" demonstrates a promising profile for AKY-1189 in patients with Nectin-4 expressing tumors. Pursuant to Section 21 guidelines of the South African Health Products Regulatory Authority (SAHPRA), 20 patients diagnosed with mUC, metastatic breast cancer, non-small cell lung cancer carcinoma, colorectal cancer and cervical cancer were imaged with [<sup>68</sup>Ga]Ga-AKY-1189 to address patient need. The resulting data were later assessed. A total of 15 patients were evaluable for biodistribution and tumor uptake analysis. Eight patients were dosed with [<sup>177</sup>Lu]Lu-AKY-1189 and were evaluable for kidney and bone marrow dosimetry. The assessment demonstrated AKY-1189 to be generally well tolerated with no treatment-emergent adverse events, and dosimetry analyses suggest a wide therapeutic index for [<sup>225</sup>Ac]Ac-AKY-1189. Significant tumor uptake of AKY-1189 was observed across primary and metastatic lesions in multiple cancer types evaluated. These data mark the first Nectin-4 targeted radiopharmaceutical to demonstrate significant tumor uptake and supports the progression of [<sup>225</sup>Ac]Ac-AKY-1189 to therapeutic clinical studies across several solid tumor types. The oral presentation is scheduled on Friday, October 25 from 1:12-1:24 p.m. CEST.

"These data provide evidence of sufficient tumor uptake of AKY-1189, not only in mUC but in other tumor types, and that AKY-1189 has promising biodistribution in normal organs and tissues," said Professor Sathekge. "This discovery marks a critical step forward in the fight against Nectin-4 expressing cancers, and sheds light on radiopharmaceuticals as a potential mainstream oncology treatment."

Aktis also showcased AKY-1189's potential as a targeted radiopharmaceutical through two poster presentations displayed within the Exhibition Hall, which are both available online for viewing. The first poster (**Abstract no. 118**), titled, "**Discovery and pre-clinical development of AKY-1189, a potent and selective Nectin-4 miniprotein binder optimized for use as a targeted radiopharmaceutical,**" highlighted AKY-1189's preclinical data supporting advancement to clinical development.

The second poster (**Abstract no. 308**), titled, "**Allometric scaling of preclinical dosimetry for the Nectin-4 miniprotein binders AKY-807 and AKY-1189 accurately predicts human absorbed dose to major organs,**" highlighted the accuracy of allometric scaling methods in predicting human organ dosimetry from preclinical data.

"The presentations at the EORTC-NCI-AACR Meeting underscores the potential of AKY-1189 in targeting Nectin-4 expressing cancers," said Matthew Roden, PhD, President and Chief Executive Officer of Aktis Oncology. "As the first therapeutic product candidate discovered from our novel miniprotein radioconjugate platform, AKY-1189 data suggest that we can achieve a favorable clinical profile and opens a new path forward in the field of radiopharmaceuticals. We look forward to advancing this promising product candidate through therapeutic clinical studies."

### **About Aktis Oncology**

Aktis Oncology, Inc. is a clinical-stage oncology company focused on unlocking the breakthrough potential of targeted radiopharmaceuticals for large patient populations not addressed by existing platform technologies. The company's first of several pipeline programs targets Nectin-4, a tumor-associated antigen found in urothelial and other solid cancers. Founded and incubated by MPM BioImpact, the company has developed its proprietary miniprotein radioconjugate platform to generate tumor targeting agents with properties ideal for alpha radiopharmaceuticals. Designed to maximize tumor killing through high penetration followed by internalization and retention in cancer cells, Aktis' miniprotein radioconjugates are designed to quickly clear from normal organs and tissues, thereby maximizing anticancer activity while minimizing side effects of treatment. The Aktis platform is isotope-agnostic and

further enables clinicians to visualize and verify target engagement with imaging isotopes prior to exposure to therapeutic radioisotopes. Aktis also has a strategic collaboration with Eli Lilly and Company to leverage its miniprotein platform to develop novel radioconjugates outside of Aktis' proprietary pipeline. To learn more about Aktis Oncology, visit [www.aktisoncology.com](http://www.aktisoncology.com).

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