Aktis Oncology Initiates Phase 1b Clinical Trial Of Its Nectin-4- Targeting Radiopharmaceutical Product Candidate, Aky-1189, Across Multiple Tumor Types

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US FDA cleared INDs for [225 Ac]Ac-AKY-1189 and [64 Cu]Cu-AKY-1189 for initiation of broad NECTINIUM-2 Phase 1b trial.

NECTINIUM-2 will evaluate [225 Ac]Ac-AKY-1189 for the treatment of patients with locally advanced or metastatic urothelial carcinoma, triple negative breast cancer and other Nectin-4 expressing tumors.

AKY-1189 is a potential first-in-class novel Nectin-4 targeted radiopharmaceutical product candidate that has previously demonstrated substantial tumor uptake across several solid tumor types.

BOSTON, Mass. – May 28, 2025 (GLOBE NEWSWIRE) — May 28, 2025 (GLOBE NEWSWIRE) — Aktis Oncology, Inc., ar oncology company focused on unlocking the breakthrough potential of targeted radiopharmaceuticals for patient populations not addressed by existing platform technologies, today announced that it has initiated clinical development of AKY-1189 in its Phase 1b clinical trial for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC), triple negative breast cancer (TNBC) and potentially other Nectin-4 expressing tumors.

Nectin-4 is a cell-surface protein highly expressed in several solid tumors with limited expression in normal tissues, making it an attractive target for precision oncology therapies. NECTINIUM-2 is a Phase 1b clinical trial that will enroll mUC patients during dose escalation, followed by dedicated expansion cohorts in mUC, TNBC and other Nectin-4 expressing tumors, including but not limited to lung, colorectal and cervical cancers. The trial is expected to enroll approximately 150 patients and patients will receive up to six doses of [225 Ac]Ac-AKY-1189. The multi-center study is being conducted in the U.S.

“Advancing the first product candidate from our proprietary miniprotein radioconjugate platform into Phase 1b clinical development in the U.S. is an important milestone for Aktis,” said Akos Czibere, MD, PhD, Chief Medical Officer of Aktis Oncology. “Data presented to date demonstrates AKY-1189’s substantial tumor uptake in patients with various Nectin-4-expressing tumor types with limited exposure to normal tissue, suggesting potential for a wide therapeutic window in addressing high unmet need patient populations.”

Data presented in an oral plenary session at the 2024 EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics demonstrated that AKY-1189 has a promising biodistribution profile with significant tumor uptake in patients with mUC, metastatic breast cancer, non-small cell lung cancer carcinoma, colorectal cancer and cervical cancer. These data marked the first report of a Nectin-4 targeted radiopharmaceutical candidate to demonstrate significant tumor uptake in patients and support the progression of AKY-1189 into therapeutic clinical studies, potentially offering a new treatment option for patients with these challenging solid tumor types.

“Radiopharmaceutical therapy targeting Nectin-4 is a highly attractive strategy, enabling the targeted delivery of radiation directly to tumor cells. Building on the success of Nectin-4-directed antibody-drug conjugates, this approach combines imaging with therapeutic innovation to potentially personalize treatment for advanced urothelial cancer and other solid tumors. The NECTINIUM-2 trial, evaluating the safety and efficacy of the Nectin-4 radiopharmaceutical, [225 Ac]Ac-AKY-1189, is a key step forward in advancing this concept,” said Matthew Galsky, M.D., co-director of the Center of Excellence for Bladder Cancer at The Tisch Cancer Institute at Mount Sinai Hospital in New York.

About Aktis Oncology

Aktis Oncology, Inc. is an oncology company focused on unlocking the breakthrough potential of targeted radiopharmaceuticals for large patient populations not addressed by existing platform technologies. Aktis’ most advanced pipeline program targets Nectin-4, a tumor-associated antigen found in urothelial and other solid cancers. Founded and incubated by MPM BioImpact, Aktis 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.

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