Ankyra Therapeutics Announces First Patient Dosed in Phase 1b Trial Evaluating First-in-Class Anchored Immunotherapy in Combination with Immune Checkpoint Blockade in Patients with Lung Cancer

- **Phase 1b LANTERN clinical study is assessing tolododekin alfa, anchored IL-12 immunotherapy, in combination with anti PD-1/PD-L1 immune checkpoint blockade for treatment of non-small cell lung cancer**
- **ANK-101-004 is a Phase 1b clinical study assessing tolododekin alfa in combination with anti PD-1/PD-L1 immune checkpoint blockade in patients with non-small cell lung cancer**
- **The study is exploring both first- and second-line treatment in independent cohorts**

November 17, 2025 (Cambridge, MA) – Ankyra Therapeutics, a clinical-stage biotechnology company pioneering anchored drug conjugate technology for cancer and other diseases, today announced that the first patient has been dosed in its ANK-101-004 clinical trial (NCT07027514). This study will evaluate the combination of Ankyra's tolododekin alfa (ANK-101), an anchored IL-12 drug conjugate with the anti-PD1 agent, cetrelimab, in patients who have progressed after initial treatment of metastatic, non-mutated non-small cell lung cancer (NSCLC). In addition, the study will evaluate tolododekin alfa in combination with standard of care immune checkpoint blockade in first-line treatment of patients with metastatic, non-mutated NSCLC and a tumor proportion score (TPS) of ≥ 50%.

"While there has been considerable progress in the treatment of lung cancer many patients do not respond to current approaches", said Thomas Marron, MD, PhD, Director of the Early Phase Trials Unit at the Tisch Cancer Institute at Mount Sinai and Chief Medical Officer of OCCAM Immune and the principal investigator of the study. "The potential use of anchored IL-12 to drive better responses without adding appreciable toxicity could be an important advance for patients."

"Tolododekin alfa has already demonstrated objective responses as a single agent in patients with anti-PD-1-refractory cancers in phase 1 trials", stated Howard L. Kaufman, MD. CEO at Ankyra Therapeutics, "and now we have an opportunity to test tolododekin in patients with advanced lung cancer." Ankyra is working with OCCAM Immune at Mount Sinai in support of Ankyra the LANTERN clinical trial, which is evaluating ANK-101 in combination with PD-1 blockade in patients with first- and second-line NSCLC. Through state-of-the-art immune profiling, OCCAM Immune aims to generate a comprehensive immune atlas to correlate immune modulation with therapeutic efficacy and disease progression, advance biomarker discovery and deepen mechanistic insights into Ankyra's novel therapeutic approach.

The ANK-101-004 (LANTERN) trial will be conducted at several institutions, including, Icahn School of Medicine at Mount Sinai, Roswell Park Cancer Institute, Mayo Clinic, Moffitt Cancer Center, The University of Chicago, Community Health Network, The University of Miami Sylvester Comprehensive Cancer Center, Karmanos Cancer Institute, FirstHealth of the Carolinas, and OSF Saint Francis Medical Center with additional sites expected as well.

About Tolododekin alfa (ANK-101)

Tolododekin alfa (ANK-101) is an anchored drug conjugate composed of interleukin-12 (IL-12) linked to aluminum hydroxide. ANK-101 enables local delivery of functional IL-12 to the tumor microenvironment where it remains biologically active for several weeks with transient exposure to the systemic circulation, thereby avoiding systemic toxicity. Treatment with ANK-101 in animal models has been associated with immune activation and rapid tumor regression. ANK-101 is being evaluated for the treatment of advanced solid tumors alone and in combination with anti-PD-1 agents. The first-in-human clinical trial of ANK-101 (NCT06171750) consists of monotherapy dose escalation, dose expansion in combination with cemiplimab, and dose optimization cohorts. The ANK-101-004 clinical trial (NCT07027514) will focus on non-mutated metastatic non-small cell lung cancer.

About Ankyra Therapeutics

Ankyra Therapeutics is a biotechnology company that has developed a highly differentiated technology platform that expands the therapeutic window of therapeutic drugs by forming a stable depot after local administration leading to prolonged immune activation and potent local and systemic immunity with reduced systemic toxicity. Ankyra is headquartered in Cambridge, Massachusetts. For more information, please visit www.ankyratx.com.

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