



**Ankyra Therapeutics Announces First Patient Dosed in Phase 1 Clinical Trial Dose Escalation Cohort Evaluating ANK-101, an Anchored Immune Medicine, for Solid Tumors**

*Safety and tolerability to be determined at up to 10 study sites in the United States and Canada*

**CAMBRIDGE, MA – March 5, 2024** – Ankyra Therapeutics, a clinical stage biotechnology company pioneering anchored immunotherapies to treat cancer, today announced the first patient dosed in the dose escalation cohort in a Phase 1 clinical study evaluating ANK-101, a tumor-directed, anchored immune medicine for solid tumors.

“The first patient dosed in the Phase 1 monotherapy study of ANK-101 marks a significant milestone in our mission to provide a potential treatment to patients with minimal unwanted side effects,” said Howard L. Kaufman, M.D., President and Chief Executive Officer of Ankyra Therapeutics. “This is not only a critical step in the development of our first-in-class asset, ANK-101, but also in our ultimate commitment to bring other biologically active agents as anchored immunotherapies to those who need them most.”

ANK-101, an interleukin-12 (IL-12) cytokine anchored to aluminum hydroxide, is locally delivered and retained in the tumor microenvironment for several weeks where it mediates recruitment and activation of effector immune cells. ANK-101 is currently under investigation in patients with advanced solid tumors who have failed standard of care treatments. In multiple preclinical models, ANK-101 demonstrated increased immune cell infiltration into tumors without systemic toxicity.

The dose escalation cohort portion of the study will assess the safety of ANK-101 and determine the recommended dose for expansion in people with cutaneous, subcutaneous, soft tissue, or nodal malignancies, with an additional 10 participants ultimately dosed at the recommended dose for expansion (RDE). The study will secondarily evaluate the PK, immunogenicity, and preliminary clinical activity of the medicine.

“These data will provide a roadmap for advancing ANK-101 through clinical development and for identifying appropriate clinical indications for future trials,” said Joe Elassal, M.D., MBA, Chief Medical Officer of Ankyra Therapeutics. “We believe this approach will enable patients to receive effective immunotherapy while potentially mitigating significant side effects during treatment.”

“ANK-101 capitalizes on a novel delivery mechanism, and this anchored immune medicine approach to oncology represents potential for positive impact across indications,” said Jong Chul



Park M.D., assistant professor at Harvard Medical School and attending physician at Mass General Cancer Center, an investigator of the Phase 1 dose escalation trial. “Patient wellbeing throughout the treatment journey is paramount, and I look forward to our ongoing work together.”

### **About ANK-101**

ANK-101 is an anchored drug complex 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 but does not diffuse into the systemic circulation, thereby avoiding systemic toxicity. Treatment with ANK-101 in animal models has been associated with recruitment and retention of CD8+ T cells, NK cells and M1 macrophages activating innate and adaptive anti-tumor immunity. ANK-101 is being evaluated for the treatment of advanced solid tumors alone and in combination with anti-PD-1 agents. The Phase 1 first-in-human, open-label clinical trial of ANK-101 as a monotherapy (NCT:06171750) consists of a dose escalation portion that will evaluate the safety and tolerability of ANK-101, followed by dose expansion cohorts.

### **About Ankyra Therapeutics**

Ankyra Therapeutics is a biotechnology company pioneering anchored immunotherapies to transform cancer treatment. The company’s platform is fueling a pipeline of novel therapeutics, including cytokine therapies, designed to anchor to the tumor microenvironment for sustained local delivery and retention at higher concentrations, while minimizing systemic exposure and on-target/off-tumor effects. Ankyra’s lead program ANK-101, IL-12 anchored to aluminum hydroxide, has potential to treat a broad range of cancers. For more information, please visit [www.ankyratx.com](http://www.ankyratx.com).

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