

# Ankyra Therapeutics Announces Pre-Clinical Research Published in December JCI Insight Demonstrating Potent Anti-Tumor Activity of Anchored IL-12 in Multiple Murine Cancer Models

Pre-clinical studies of ANK-101, an anchored IL-12 therapy, demonstrate the potential of anchored immune medicines to enhance the efficacy and safety profile of cancer immunotherapies

CAMBRIDGE, MA – December 12, 2023 (BUSINESSWIRE) – Ankyra Therapeutics, an emerging clinical-stage biotechnology company pioneering anchored immunotherapies to treat cancer, today announced results from a preclinical study demonstrating potent anti-tumor activity of its lead program ANK-101 were published in the December issue of the *Journal of Clinical Investigation Insight* (JCI Insight). The <u>research paper</u> is titled "Intratumoral aluminum hydroxide-anchored IL-12 drives potent antitumor activity by remodeling the tumor microenvironment."

ANK-101 is a novel tumor-directed anchored immune medicine (AIM) composed of interleukin-12 (IL-12) linked to aluminum hydroxide.

"One of the key challenges of intratumoral administration is retention within the tumor, both for efficacy and to limit systemic exposure," said Howard L. Kaufman, M.D., President and Chief Executive Officer of Ankyra Therapeutics. "Our pre-clinical data indicates that anchored immunotherapy retains active IL-12 at the tumor site for weeks, versus just hours with unanchored recombinant IL-12. This results in potent immune activation with limited systemic exposure, indicating the potential to improve patient outcomes while reducing side effects. We are excited to continue to advance this program and look forward to initiating our Phase 1 clinical study in humans in early 2024."

# Data published in JCI showed:

- Ankyra's anchored immunotherapy platform achieves retention of the drug ANK-101 at the injected site for approximately four weeks
- One or two intratumoral injections of a murine ANK-101 analogue induced single-agent anti-tumor activity across a diverse range of syngeneic mouse models
- Local treatment with the drug induced tumor regressions of distant, non-injected lesions demonstrating abscopal effects, which were enhanced when combined with systemic checkpoint blockade
- Anti-tumor activity mediated by the drug was associated with recruitment of immune cells and remodeling the tumor microenvironment
- Human ANK-101, when tested in cynomolgus macaques, was well tolerated



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 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.

# **About Ankyra Therapeutics**

Ankyra Therapeutics is an emerging clinical-stage 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, is currently being evaluated in Phase 1 clinical studies to treat a broad range of advanced cancers. For more information, please visit <a href="https://www.ankyratx.com">www.ankyratx.com</a>.

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