

Ankyra Therapeutics Announces Promising Preclinical Data on ANK-101, a Novel Anchored Immune Medicine, in Combination with Cytotoxic Chemotherapy in Head and Neck Cancer Model

First-in-class anchored IL-12 immunotherapy mANK-101 shows tumor growth delay in murine models as a monotherapy and in combination with platinum and anti-PD-1

Data presented at the Society for Immunotherapy of Cancer in San Diego pave the way for ANK-101 as combination therapy

CAMBRIDGE, MA – November 3, 2023 (BUSINESSWIRE) – Ankyra Therapeutics, an emerging clinical stage biotechnology company pioneering anchored immunotherapies to treat cancer, today announced data from a preclinical study using ANK-101, an IL-12 anchored therapeutic, in combination with cytotoxic chemotherapy and immune checkpoint blockade, to treat head and neck squamous cell carcinoma, modeled by murine oral carcinoma (MOC1). The study was conducted jointly by Ankyra Therapeutics and the Center for Immuno-Oncology, part of the National Institute of Health’s National Cancer Institute Center for Cancer Research. The findings are being presented during the Society for Immunotherapy of Cancer Annual Meeting November 1-5, 2023 in San Diego, CA.

Following treatment with combinations of murine ANK-101, cisplatin (cis-platinum), and anti-PD-1 alone or together, tumor size and mouse survival were recorded. Data presented showed that a single dose of mANK-101 was associated with a significant delay in tumor growth in the MOC1 model, while anti-PD-1 and cisplatin alone, or in combination, had minimal impact on tumor growth. When mANK-101 was combined with either cisplatin or anti-PD-1, no further delay in tumor growth compared to monotherapy mANK-101 was observed; however, triple therapy (ANK-101, cisplatin, anti-PD-1) further delayed tumor growth and increased survival when compared to mANK-101 monotherapy.

“These are promising preclinical results for ANK-101, not only as a monotherapy but also in combination with chemotherapy and checkpoint inhibitors,” said Howard L. Kaufman, M.D., President and CEO of Ankyra Therapeutics. “These data suggest that anchored IL-12 could improve the current standard of care in head and neck carcinoma while adding limited additional toxicity.”

Ankyra Therapeutics is pioneering a new class of tumor-directed, anchored immuno-oncology agents, and its lead asset comprises IL-12 linked to aluminum hydroxide. The IL-12 complex is designed for local retention of functional IL-12 within the tumor microenvironment. Previous pre-clinical data demonstrated retention of IL-12 for up to 4 weeks without evidence of systemic toxicity, maximizing therapeutic potency while minimizing systemic exposure and on-target/off-tumor side effects. The U.S. Food and Drug Administration (FDA) and Health Canada have recently approved the company’s Investigational New Drug (IND) application for ANK-101: in early 2024, Ankyra plans to initiate a first-in-human Phase I clinical trial of ANK-101 as a single

agent anchored immunotherapy in patients with advanced solid tumors who have failed standard of care treatments.

“As we prepare to enter the clinic, we are very encouraged by these results,” said Leisha A. Emens, M.D., Ph.D., Senior Vice President of Translational Research of Ankyra Therapeutics. “In our preclinical studies, ANK-101 increases immune activity within the tumor microenvironment, priming the tumor for greater clinical benefit from the combination of chemotherapy and PD-1 blockade.”

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 tumor-specific 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 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. The company’s lead program ANK-101, IL-12 anchored to aluminum hydroxide with potential to treat a broad range of cancers, will enter the clinic in 2024. For more information, please visit www.ankyratx.com.

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