

Ankyra Therapeutics Presents Positive Preclinical Data Supporting Advancement of ANK-101 into Clinical Studies for Treatment of Solid Tumors

Data to be presented during Society for Immunotherapy of Cancer 37th Annual Meeting

BOSTON, November 10, 2022 – Ankyra Therapeutics, a biotech company developing targeted immune activating agents for the treatment of cancer, today announced that new, preclinical data highlighting the potential of the company's lead program, ANK-101, an IL-12-based treatment, to deliver potent anti-tumor responses following intratumoral administration will be presented during a poster presentation at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting. SITC is being held November 10-13, 2022, virtually and in Boston.

IL-12 is a potent cytokine that can promote innate and adaptive anti-cancer immunity, but its clinical development has been limited by toxicity when delivered systemically. Intratumoral administration can expand the therapeutic window of IL-12; however, it is limited by rapid drug clearance from the tumor, thereby reducing efficacy, necessitating frequent administration, and increasing systemic accumulation. To overcome the limitations of traditional cytokine therapeutics, Ankyra has leveraged its Anchored Immunotherapy Platform to develop ANK-101, a stable complex of a modified IL-12 cytokine with aluminum hydroxide (Alhydrogel®). Alhydrogel®, an FDA-approved adjuvant for use in human and veterinary vaccines, acts as a scaffold to locally retain the potent activity of IL-12 following intratumoral administration in order to improve its therapeutic window.

“We are excited to present these findings from our ANK-101 program at this year's SITC Annual Meeting, which highlight the potential of our Anchored Immunotherapy Platform to enable an expanded therapeutic window for cytokines like IL-12,” said Howard Kaufman, M.D., president and chief executive officer. “IL-12 is well known to have the ability to offer a meaningful treatment option for patients with cancer, but that has historically been limited by toxicity and dosing challenges. By leveraging our platform based on Alhydrogel® anchoring, we believe we can overcome the shortcomings of systemic IL-12 to deliver a safe and effective treatment option. This is supported by our extensive preclinical work with ANK-101, where we've observed potent anti-tumor responses with good tolerability, and we look forward to its continued advancement towards clinical studies.”

The data to be presented today are from several preclinical studies in mouse models and non-human primates (NHPs). Findings include:

- Administration of mANK-101 (murine surrogate) led to enhanced tumor retention and reduced systemic exposure compared to un-anchored IL-12
- Administration of mANK-101 was efficacious in diverse syngeneic tumor models, including large tumors, leading to substantial reductions in tumor volume after one or two injections

- mANK-101 treatment induced a profound remodeling of the tumor microenvironment with increased T- and NK-cell infiltration and activation, shifts to pro-inflammatory myeloid cell phenotypes, and increased markers of antigen presentation and co-stimulation as measured by Nanostring, IHC, and scRNA-seq
- ANK-101 administration in NHPs was well tolerated across all dose levels evaluated

Ankyra is currently advancing ANK-101 through Investigational New Drug (IND) enabling studies and plans to submit an IND to the U.S. Food and Drug Administration in the second quarter of 2023.

About Ankyra Therapeutics

Ankyra Therapeutics is a biotechnology company developing a novel approach to treating cancer, designed to expand the therapeutic window of cytokine drugs. Cytokine treatments have shown to be effective in treating cancer, but systemic dosing is limited by broad immune activation and toxicity. Using its proprietary Anchored Immunotherapy Platform, Ankyra has developed methods to localize cytokines specifically and persistently in tumor tissue, creating intense hot spots of inflammation that awaken an anti-tumor immune response. Using its platform, the company is building a pipeline of therapeutics designed to provide prolonged immune activation and potent local and systemic immunity with reduced systemic toxicity. For more information, please visit www.ankyratx.com.

CONTACTS:

For Investor and Media Inquiries:

Alicia Davis, THRUST Strategic Communications

alicia@thrustsc.com