

Ankyra Therapeutics Presents Preliminary Canine Clinical Data with cANK-101 Supporting Therapeutic Potential of Anchored Immunotherapy

Preliminary data of anchored canine IL-12 (cANK-101) in dogs with malignant melanoma demonstrates tolerable safety and early signs of biologic activity. Human ANK-101 is an IL-12-based anchored immunotherapy with IND submission planned for late 2023

BOSTON, MA, April 13, 2023 (GLOBE NEWSWIRE) – Ankyra Therapeutics, a pre-clinical-stage oncology company developing anchored immunotherapies to improve the therapeutic window for cytokine drugs, announced today that it will be presenting data from a canine clinical trial of cANK-101 at the American Association for Cancer Research (AACR) Annual Meeting being held April 14-19, 2023, in Orlando, FL.

Ankyra Therapeutics has developed an anchored drug-delivery platform based on linking immunotherapy drugs to aluminum hydroxide. The linked compounds are delivered locally to the tumor, where they are retained for several weeks promoting anti-tumor activity while preventing systemic toxicity. cANK-101 is a novel agent comprised of canine interleukin-12 complexed with aluminum hydroxide using the Ankyra platform. An exploratory phase I clinical trial of cANK-101 in dogs with malignant melanoma was designed by and is being conducted at the University of Illinois College of Veterinary Medicine with Timothy Fan, DVM, PhD, as principal investigator.

“We have been delighted to work with Dr. Fan on bringing a potentially new immuno-oncology drug to dogs with malignant melanoma who have few other effective therapeutic options,” stated Howard L. Kaufman, MD, CEO of Ankyra Therapeutics. Dr. Kaufman also stated that “we are learning information about the pharmacology and immunology of cANK-101 in the dogs that will be relevant as we develop a comparable agent for humans with cancer.”

“Our experience with cANK-101 in dogs with advanced melanoma strongly suggests that the drug is well tolerated. We are seeing few side effects in treated dogs,” said Dr. Fan, a professor of veterinary clinical medicine at the University of Illinois. “We are excited about observed cyto-reductive activities and will be following the dogs to determine the clinical impact and durability of response that cANK-101 may have on a difficult-to-treat cancer in dogs.”

The poster presentation at the 2023 annual AACR meeting highlights the following preliminary data:

- cANK-101 is a canine interleukin-12 linked to an aluminum hydroxide scaffold designed for direct injection into established canine tumors
- An exploratory phase 1 study was designed using a standard 3+3 design with increasing doses of cANK-101 (1, 3, 10, and 20 ug/kg) given by intratumoral injection every three weeks to dogs with locally advanced or metastatic melanoma

- To date, 9 dogs have been enrolled (1 cutaneous melanoma, 8 mucosal melanoma) with dose escalation on-going
- To date, there have been no dose-limiting toxicities noted, with a subset of patients developing transient grade 1-2 local injection site reactions
- cANK-101 pharmacokinetics and immune biomarker data suggest cANK-101 induces local interferon-gamma and results in T cell recruitment to the tumor site
- One dog has achieved a strong objective response (near complete response) at the 3 ug/kg dose and clinical responses at higher doses will be reported with further follow-up
- Exploratory studies in dogs with cancer may represent an appropriate model for early study of immuno-oncology drugs in development for the treatment of human cancer

Title: Preliminary results of an exploratory phase I clinical trial of anchored canine interleukin-12 (cANK-101) in dogs with advanced oral malignant melanoma

Session Category: Immunology

Session Title: Anticancer Immunotherapeutics

Session Date and Time: Wednesday Apr 19, 2023 9:00 AM - 12:30 PM

Location: Poster Section 22

Poster Board Number: 23

Published Abstract Number: 6347

The poster will be available on the publications section of Ankyra's website at <https://ankyratx.com/#science>.

About ANK-101

ANK-101 is an investigational drug composed of human interleukin-12 (IL-12) molecules with an alum-binding peptide linked to aluminum hydroxide. ANK-101 is intended for direct intratumoral injection into established tumors. A phase I clinical trial is planned to evaluate the safety and identify a recommended Phase 2 dose for ANK-101 in patients with cancer.

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.

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