



Ankyra Therapeutics Presents Preliminary Phase 1 Canine Clinical Data Evaluating cANK-101 to Treat Advanced Malignant Melanoma in Dogs

First-in-class anchored IL-12 immunotherapy increases immune cell infiltration into tumors while decreasing systemic toxicity

Human ANK-101, an IL-12- based anchored immunotherapy, will begin Phase 1 clinical studies in 2024

CAMBRIDGE, MA – October 14, 2023 (BUSINESSWIRE) – Ankyra Therapeutics, a pre-clinical stage biotechnology company developing a new class of anchored immunotherapies to treat cancer, today presented preliminary data from an exploratory Phase 1 canine clinical study evaluating cANK-101, a canine IL-12 anchored therapeutic, to treat advanced malignant melanoma. The study is being conducted at the University of Illinois College of Veterinary Medicine. Timothy Fan, DVM, PhD, a professor of veterinary clinical medicine and Associate Director for Translation and Development at the Cancer Center at the University of Illinois, is the principal investigator. Dr. Fan presented findings in an oral session during the annual Veterinary Cancer Society conference in Reno, NV.

Data presented by Dr. Fan demonstrated the safety, tolerability, and activity of cANK-101 in dogs (n=10) with advanced malignant melanoma and will inform the design of future human clinical trials. Four dogs experienced grade 1 or 2 treatment-related AEs; no dose-limiting toxicity or serious adverse events were observed.

Administration of cANK-101 was shown to increase immune response, resulting in higher levels of serum interferon gamma (IFN γ), interleukin-10 (IL-10), and circulating CD4+ T cells. Tumor biopsies showed an increase in CD3+ T cells and IBA1+ macrophages following treatment with cANK-101. Nanostring gene expression studies suggested an increase in transcriptome-favored immune activation genes, providing early evidence of immune activation against cancer cells following treatment with anchored IL-12 in an immune-competent host with an established cancer.

“We are highly encouraged by the safety and tolerability profile of our anchored IL-12 in canines and plan to initiate a Phase 1 clinical study in humans in early 2024,” said Howard L. Kaufman, MD, CEO of Ankyra Therapeutics. He added, “The early evaluation of immuno-oncology agents in dogs with cancer provides a useful model for early clinical validation and has helped guide our clinical development plans.”

Ankyra Therapeutics is pioneering a new class of anchored immunotherapies, medicines designed to anchor directly to the tumor site for sustained release and retention within the tumor microenvironment, maximizing therapeutic potency while minimizing systemic exposure and off-



target side effects. cANK-101 is a novel fusion of IL-12 and aluminum hydroxide designed for intratumoral administration.

“The continued collection of data on cANK-101 in dogs with advanced malignant melanoma provides us confidence in the efficacy, safety, and tolerability profile of this novel compound,” said Dr. Fan. “The noticeable increase in downstream cytokines that trigger an immune response in dogs with melanoma mean that there may be new drug development opportunities to impact clinical outcomes for companion dogs.”

An abstract from the VCS presentation is available on the publications section of Ankyra's website at <https://ankyratx.com/#science>.

About cANK-101

cANK-101 is an investigational drug composed of canine interleukin-12 (IL-12) molecules with an alum-binding peptide linked to aluminum hydroxide. cANK-101 is intended for direct intratumoral injection into established tumors in canine patients. A phase 1 exploratory study evaluating the safety, tolerability, and activity of cANK-101 is currently ongoing.

About ANK-101

ANK-101 is an investigational anchored immunotherapy fusing human interleukin-12 (IL-12) with aluminum hydroxide to anchor the medicine directly to the tumor site for sustained delivery once injected intratumorally. A phase I clinical trial is planned to evaluate the safety and identify a recommended Phase 2 dose for ANK-101 in humans with cancer.

About Ankyra Therapeutics

Ankyra Therapeutics is a biotechnology company advancing a new class of 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 at higher concentrations, while minimizing systemic exposure and off-target effects. The company's lead program ANK-101, an IL-12 fusion 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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