Ankyra Therapeutics Announces Clinical Trial Collaboration and Supply Agreement with Merck to Evaluate ANK-101 in Combination with KEYTRUDA® (pembrolizumab) in Patients with Advanced Solid Tumors

ANK-101 is a novel first-in-class anchored IL-12 immunotherapy designed for limited intratumoral delivery to increase immune cell infiltration into tumors, with potential to improve outcomes of patients treated with immune checkpoint inhibitors

CAMBRIDGE, Mass. – October 4, 2023, (BUSINESSWIRE) – Ankyra Therapeutics, a clinical biotechnology company developing a new form of local immunotherapy termed "anchored immunotherapy," today announced a clinical trial collaboration and supply agreement with Merck (known as MSD outside of the US and Canada) to evaluate ANK-101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) following the completion of a first-in-human phase I study of ANK-101 alone in patients with advanced solid tumors.

Pending completion of a first-in-human phase I study, ANK-101 would advance to KEYNOTE-E56, a clinical trial designed to evaluate ANK-101 in combination with pembrolizumab in patients with advanced solid tumors. The study is anticipated to begin enrollment in 2024.

The Ankyra platform uses an inert scaffolding composed of aluminum hydroxide, a well-known vaccine adjuvant, and links bioactive immune agents to the anchor. Preclinical studies of ANK-101, a functional human interleukin-12 (IL-12) cytokine, have demonstrated retention within the tumor microenvironment for up to 28 days with limited diffusion and systemic toxicity. Significant monotherapy anti-tumor activity has been seen in multiple murine tumor models and in a Phase I clinical trial of canine melanoma. Further studies have shown that ANK-101 drives expression of local PD-L1 and pre-clinical combination studies with PD-1 blockade have demonstrated improved therapeutic activity in PD-1-refractory tumor models.

"ANK-101 has demonstrated therapeutic activity in several preclinical models and has been shown to strongly induce expression of PD-1 within the tumor microenvironment," said Robert Tighe, CSO at Ankyra. "We have also seen significant improvement in tumor responses and abscopal activity in the preclinical models when murine ANK-101 is combined with PD-1 blockade without increased toxicity."

"We are especially excited about evaluating our drug in combination with pembrolizumab in the KEYNOTE-E56 trial," stated Dr. Joe Elassal, CMO at Ankyra. "Pembrolizumab has changed the clinical landscape for many different cancers, and we anticipate that the combination of ANK-101 and pembrolizumab may allow more patients to benefit from immunotherapy".

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About ANK-101
ANK-101 is an intratumoral drug complex composed of interleukin-12 (IL-12) linked to aluminum hydroxide. ANK-101 allows 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 pembrolizumab.

About Ankyra Therapeutics
Ankyra Therapeutics is a biotechnology company that has developed a highly differentiated technology platform that expands the therapeutic window of cytokine drugs by forming a stable depot in the tumor after local administration leading to prolonged immune activation and potent local and systemic immunity with reduced systemic toxicity.

Ankyra was founded in 2019 and is headquartered in Cambridge, Massachusetts. For more information, please visit www.ankyratx.com

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