

Ankyra Therapeutics Announces Clinical Trial Supply Agreement with Regeneron to Evaluate ANK-101 in Combination with Libtayo® (cemiplimab) in Patients with Cutaneous Squamous Cell Carcinoma

ANK-101 is a novel first-in-class anchored IL-12 immunotherapy designed for limited anchored delivery to increase immune cell infiltration into tumors and may further increase responses to immune checkpoint inhibitors

CAMBRIDGE, MA – November 13, 2023 (BUSINESSWIRE) – Ankyra Therapeutics, a clinical stage biotechnology company developing a new form of local immunotherapy termed “anchored immunotherapy,” today announced a clinical trial supply agreement with Regeneron to evaluate ANK-101 in combination with Regeneron’s anti-PD-1 therapy, Libtayo® (cemiplimab).

The Ankyra platform uses an inert aluminum hydroxide scaffolding to link to bioactive immunology agents. Preclinical studies of ANK-101, a functional interleukin-12 (IL-12) cytokine, have demonstrated retention within the tumor microenvironment for up to 28 days with limited systemic diffusion or 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 demonstrated improved therapeutic activity in PD-1-refractory tumor models.

“We are excited to expand our clinical collaborations to evaluate the combination of ANK-101 with cemiplimab in cutaneous squamous cell carcinoma (CSCC),” said Dr. Joe Elassal, Chief Medical Officer at Ankyra. “Cemiplimab has been a major step forward for patients with advanced CSCC and we believe that this is a tumor where combination therapeutic effects are highly likely.”

The combination study will proceed following Ankyra’s first-in-human phase I clinical trial, which is starting in the first quarter of 2024.

Dr. Howard L. Kaufman, President and Chief Executive Officer at Ankyra added, “We are especially pleased to be working with Regeneron, leaders in the CSCC space, and look forward to building a strong relationship with Regeneron to improve the lives of patients with this common form of skin cancer.”

Libtayo® is a registered trademark of Regeneron in Tarrytown, NY.

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 anti-PD-1 agents.

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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