Ankyra Therapeutics Announces Phase 1 Clinical Data at the 2025 AACR Annual Meeting and the first patient has been dosed with tolododekin alfa and cemiplimab

Ankyra Therapeutics announced preliminary clinical data today from Part 1 of their Phase 1 ANCHOR study evaluating an anchored IL-12 drug conjugate, tolododekin alfa, as monotherapy in patients with solid tumors

Ankyra also announced the first patient has been dosed with tolododekin alfa and cemiplimab

April 28, 2025 (Cambridge, MA) – Ankyra Therapeutics, a leading clinical-stage company developing anchored drug conjugates for the treatment of cancer, today presented preliminary data highlighting the safety and biologic activity of their lead asset, tolododekin alfa (ANK-101), an anchored interleukin-12 (IL-12) drug conjugate. The data was derived from Part 1 of the first-in-human (FIH) ANCHOR Phase 1 clinical trial. The study was designed to evaluate the safety and feasibility of tolododekin alfa, as monotherapy in patients with advanced solid tumors. Dr. Howard Kaufman, Ankyra President and CEO stated that "we are extremely pleased with the data which provided support for the potential of the anchored drug conjugate platform". He added "the study demonstrates for the first time that IL-12 can be delivered to tumors at therapeutic doses higher than previously achievable without systemic toxicity". Systemic delivery of IL-12 has been evaluated in previous clinical studies, but development was halted after a maximum tolerated dose of 500 ng/kg prevented further dose escalation of IL-12 in cancer patients. Dr. Joe Elassal, Ankyra Chief Medical Officer added that tolododekin alfa "Phase 1 data are encouraging and we have seen that IL-12 anchoring has resulted in 6-fold higher local IL-12 delivery to established cancers compared with what has been achieved with systemic administration." Furthermore, biomarker analysis of tumor-treated biopsies showed increased CD8+ T cell infiltration and induction of local PD-L1 expression. Dr. Elassal added "the high levels of PD-L1 seen provide strong justification for our expansion cohort combining tolododekin alfa with immune checkpoint blockade". Ankyra reports that on March 25, 2025 the first patient with advanced cutaneous squamous cell carcinoma was treated with a combination of tolododekin-alfa and Regeneron's PD-1 inhibitor, Libtayo® (cemiplimab), in an expansion cohort to the current Phase 1 trial.

Results from Part one of the Phase 1 FIH study are being presented on Monday, April 28, 2025 at the American Association of Cancer Research (AACR) Annual Meeting in Chicago, IL.

Abstract Title: Results of a first-in-human phase 1 trial of anchored IL-12 drug conjugate (ANK-101).

- Session Title: Phase 0 and Phase I Clinical Trials
- Session Start: 4/28/2025 9:00:00 AM
- Session End: 4/28/2025 12:00:00 PM
- Location: Poster Section 49
- Poster Board Number: 18
- Abstract Presentation Number: CT039

The poster will be available on the publications section of Ankyra's website after the meeting at https://ankyratx.com/news/

Key Study Findings

- Fifteen (15) patients with metastatic solid tumors who had progressed on standard therapy and had accessible lesions for injection were enrolled across four study sites in the U.S. and Canada
- Primary tumor histology included melanoma (n=7), head and neck cancer (n=4), breast cancer (n=2), bladder cancer (n=1), and apocrine adenocarcinoma (n=1)
- ANK-101 monotherapy was well-tolerated at doses up to 250 µg/mL with no DLTs or Grade 3 or greater treatment-related treatment-emergent adverse events (TEAEs)
- Highly efficient tumor retention with low (generally <1%) systemic IL-12-ABP
- ANK-101 induced CD8+ T cell recruitment, PD-L1 expression, and inflammatory gene signatures consistent with biologic IL-12 activity
- Initial results suggest clinical activity with 2 PRs and a disease control rate of 80% by modified RECIST v1.1

About Tolododekin alfa (ANK-101)

Tolododekin alfa (ANK-101) is an anchored drug conjugate composed of interleukin-12 (IL-12) linked to aluminum hydroxide. ANK-101 enables 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 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. The first-in-human, open-label clinical trial of ANK-101 as a monotherapy (NCT:06171750) consists of a dose escalation portion that will evaluate the safety and tolerability of ANK-101, followed by dose expansion cohorts. Additional clinical trials are being planned in different cancer types.

ANK-101 will be prominently featured on an upcoming documentary "The Cancer Pioneers" as part of the Public Broadcasting System (PBS) series "Shelter Me". The program will air nationally on local PBS television stations on May 1, 2025 and more information can be found at https://www.facebook.com/ShelterMeTV/videos/coming-soon-to-pbs-shelter-me-the-cancer-pioneersthis-film-is-about-groundbreaki/1342447700302755/.

About Ankyra Therapeutics

Ankyra Therapeutics is a biotechnology company that has developed a highly differentiated technology platform that expands the therapeutic window of therapeutic drugs by forming a stable depot 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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