PRESS RELEASE

Abalos Therapeutics Doses First Patient in Phase 1 Study Evaluating ABX-001 for the Treatment of Solid Tumors

-- First-in-class non-oncolytic arenavirus-based approach designed to induce targeted, effective, and durable anti-cancer activity against primary tumors and metastases –

-- Phase 1 study to evaluate the safety and tolerability of ABX-001 and determine the recommended Phase 2 dose in patients with refractory/relapsed solid tumors --

Düsseldorf, Germany, October 23, 2025 – Abalos Therapeutics announced today that the first patient has been dosed in the first-in-human study in patients with advanced solid tumors who have exhausted standard of care. The trial is evaluating ABX-001, the company's lead non-lytic viroimmunotherapy candidate, designed to systemically activate strong innate (immediate) and adaptive (memory) immune responses against cancer cells and actively guide immune cells into the tumor. In preclinical models, ABX-001 showed increased tumor T cell infiltration and T cell-mediated anti-tumor activity, while maintaining a favorable safety profile.

"Transitioning into a clinical-stage company is a strong validation of Abalos' scientific approach and team and advances our mission to overcome current limitations in immunotherapy for a broad cancer patient population," commented Gerben Moolhuizen, CEO at Abalos. "We believe that ABX-001 offers unique immunostimulatory and anti-tumoral properties, enabled by persistent and sustained replication of ABX-001 in cancerous and antigen-presenting cells, without destroying them. With this novel approach, we aim to safely engage all key immune organs in a concerted attack against a patient's tumor, including migrating and metastasized cancer cells. This first-in-human trial will provide a critical foundation for ABX-001's further clinical development. We are excited about the potential impact for patients and look forward to providing updates as the trial progresses."

The Phase 1 clinical trial (EUCT 2024-512403-39-01) is a first-in-human, open-label, multicenter study to evaluate safety and tolerability, and determine the recommended Phase 2 dose (RP2D) of ABX-001, which is administered intravenously as monotherapy in approximately 18 patients with refractory/relapsed advanced solid tumors. Patients will receive a single intravenous administration of ABX-001 in a dose-escalation approach. In addition to safety and tolerability, early signs of efficacy will be assessed, defined by overall response (OR) based on RECIST 1.1 criteria and immune RECIST, as well as best percentage change from baseline in size of target lesions, up to 12 weeks from the start of treatment.

The clinical trial initiation follows the recent publication of preclinical proof-of-concept results for ABX-001 in *Cell Reports Medicine*. In various murine tumor *in vivo* models, ABX-001 achieved strong anti-tumoral efficacy by inducing the expansion of tumor-specific T cells and immune-activating cytokines, including type I interferons. Treatment of non-human primates (NHP) with ABX-001 led to substantially increased levels of immunostimulatory cytokines and chemokines, as well as significantly increased expansion of CD4+ and CD8+ T cells. Abalos' lead candidate demonstrated a highly favorable safety profile, with minimal viral replication in healthy tissues and no severe disease symptoms in mice and NHPs highly susceptible to wild-type arenavirus.

About Abalos Therapeutics
Abalos Therapeutics is pioneering a novel anti-cancer approach that directs the full breadth of the immune system's power specifically towards cancer cells. Abalos' arenavirus-based drug candidates are designed to trigger precise innate and adaptive immune responses from within the tumor. They engage all relevant immune cell types in a concerted attack against both the primary tumor and distant metastases and actively guide them into the cancer tissue. Abalos' lead product candidate ABX-001 has demonstrated strong anti-tumor efficacy in pre-clinical studies in multiple tumor models as well as an excellent pre-clinical safety profile and is now being evaluated in a Phase 1 trial in multiple solid tumors. Led by experienced biotech entrepreneurs and immunology pioneers, Abalos' goal is to establish a new drug class in immuno-oncology. For more information, please visit www.abalos-tx.com.

For more information, please contact:

Abalos Therapeutics GmbH
Phone: +49 211 540104-0
Email: info@abalos-tx.com

Abalos media inquiries
Trophic Communications
Stephanie May / Marie-Theresa Weickert
Phone: +49 171 185 56 82
Email: abalos@trophic.eu