RNS Number : 3960G
Avacta Group PLC
28 April 2025

Avacta Therapeutics Presents Data from Lead pre|CISION® Candidate FAP-Dox (AVA6000) at the 2025 AACR Annual Meeting

Compelling Phase 1 safety and efficacy data for FAP-Dox (AVA6000) with preliminary evidence of efficacy in salivary gland cancers and no severe cardiac toxicity

Progression free survival (PFS) data to date represents a near doubling of the benchmarking data in this patient population without reaching median PFS

LONDON and PHILADELPHIA - April 28, 2025 - Avacta Therapeutics (AIM: AVCT), a life sciences company developing next generation peptide drug conjugates (PDC) targeting powerful anti-tumor payloads directly to the tumor, today announced Phase 1 data from its lead program FAP-Dox (AVA6000), that were presented alongside preclinical pharmacokinetic results from its second pre|CISION® candidate AVA6103 (FAP-EXd) at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, IL.

Both programs are designed to target fibroblast activation protein-alpha (FAPα), the protease that forms the basis of the pre|CISION® platform. FAP is consistently overexpressed across a broad range of solid tumors and enriched at the tumor-stroma interface, making it an ideal target for tumor-localized drug activation. Avacta's proprietary pre|CISION® chemistry leverages this tumor-specific biology to activate potent drugs selectively at the tumor site, enhancing efficacy while minimizing systemic toxicity.

"Today's clinical results mark the achievement of a proof-of-concept milestone with our proprietary pre|CISION® platform demonstrating meaningful activity," said Christina Coughlin, CEO of Avacta Therapeutics. "With AVA6000 demonstrating strong early signs of efficacy in a specific patient population of salivary gland cancers and a differentiated safety profile, we are not only validating a tumor-targeted approach to cytotoxics delivery - we are establishing a foundation for this new class of precision oncology therapeutics. These data underscore the tremendous potential of our pipeline to deliver meaningful benefits for patients and drive sustained value creation for our key stakeholders."

AVA6000 (FAP-Dox) Clinical Highlights (Abstract #CT15, Apil 29, 2025)

AVA6000 is a FAP-activated form of doxorubicin designed to reduce the systemic side effects of conventional chemotherapy. In the Phase 1a dose-escalation study, AVA6000 was well-tolerated across both every-three-week (Q3W) and every-two-week (Q2W) dosing regimens. No maximum tolerated dose (MTD) was reached despite dosing up to 385 mg/m² every three weeks.

In patients with salivary gland cancers (SGC, n=11) treated at or above the dose level of 250 mg/m2, AVA6000 demonstrated multiple confirmed responses and a disease control rate of 91%. Median progression-free survival (PFS) has not yet been reached, with median follow-up exceeding 25 weeks (25.3 weeks, 5.9 months). These FAP-Dox PFS results compare favorably to recent benchmarking data in this patient population presented at ESMO 2024, with a reported PFS of 3.5 months (15 weeks) in a large cohort (n=54) in a similar setting of pretreated patients with SGC (Licitra et al. ESMO 2024).

Despite dosing up to 4x the dose of conventional doxorubicin, the exposure of released doxorubicin in plasma and normal tissues is lower than that observed with conventional dose doxorubicin (75 mg/m2 Q3W) and the median tumor to plasma ratio is 100:1. In addition, no severe cardiac toxicity was observed, further supporting a markedly improved safety profile over conventional doxorubicin. The lack of toxicity is explained by the limited tissue distribution as well as limited first pass effect exposure of released doxorubicin.

The full Phase 1a data across all patients (n=63), including a full assessment of the cardiac safety data with long-term follow-up are expected in the second half of 2025.

Avacta continues to enroll patients in three Phase 1b expansion cohorts in salivary gland cancer, triple negative breast cancer and high-grade soft tissue sarcoma with data anticipated by the end of 2025.

Abstract Number and Title: #CT15: Comparative pharmacokinetics and tumor activation of fibroblast activation protein (FAP)-enabled pre|CISION® peptide drug conjugates

- **Session Title**: First-in-Human Phase I Clinical Trials 2
- **Session Date and Time:** Tuesday, April 29, 2025, 9:00 a.m. - 12:00 p.m. CT

-Ends-

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About Avacta - www.avacta.com

Avacta Therapeutics is a clinical-stage life sciences company expanding the reach of highly potent cancer therapies with the pre|CISION® platform. pre|CISION® is a proprietary warhead delivery system based on a tumor-specific protease (fibroblast activation protein or FAP) that is designed to concentrate highly potent warheads in the tumor microenvironment while sparing normal tissues. Our innovative pipeline consists of pre|CISION® peptide drug conjugates (PDC) or Affimer® drug conjugates (AffDC) that leverage the tumor-specific release mechanism, providing unique benefits over traditional antibody drug conjugates.

About the pre|CISION® Platform

The pre|CISION® platform comprises an anticancer payload conjugated to a proprietary peptide that is a highly specific substrate for fibroblast activation protein (FAP) which is upregulated in most solid tumors compared with healthy tissues. The pre|CISION® platform harnesses this tumor specific protease to cleave pre|CISION® peptide drug conjugates and pre|CISION® antibody/Affimer® drug conjugates in the tumor microenvironment, thus releasing active payload in the tumor and reducing systemic exposure and toxicity, allowing dosing to be optimized to deliver the best outcomes for patients.