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Avacta announces two key clinical updates to its faridoxorubicin program

Cardiac dosing limit removed and path forward to dose selection identified

LONDON and PHILADELPHIA - February 3, 2026 - Avacta Therapeutics (AIM: AVCT, "the Company", "Avacta"), a clinical stage biopharmaceutical company developing pre|CISION®, a tumor-activated oncology delivery platform, has published two key clinical updates to its faridoxorubicin (AVA6000) clinical program.

Agreed updates to the trial protocol include the removal of the maximum dosing limit and to allow flexibility in dosing levels. These two developments underscore the growing confidence from investigators and regulators in the tolerability profile of faridoxorubicin and should support a smooth transition to future efficacy studies.

The historic maximum dosing limit which is based on the patient's exposure to released (free) doxorubicin, has been removed in the clinical trial following the collection of highly favorable safety data from the faridoxorubicin program and observation of patients receiving the highest cumulative doses for prolonged periods. Dosing in the Phase 1 clinical trial escalated to a dose of nearly 4x the conventional dose of doxorubicin and the maximum cumulative exposure of released doxorubicin was increased to 550 mg/m^2 during the trial with no severe cardiac toxicity observed.

One of the key advantages of the pre|CISION® platform is that its unique delivery mechanism allows patients to receive the drug for longer and at higher doses due to improved tolerability, with the potential to extend the progression free survival endpoint in trials.

The Company's second significant update relates to the determination of the dose for the study in efficacy trials. The final cohorts of patients with the selected indications in Phase 1b will be enrolled, enabling two dose levels to be compared in order to determine the optimal biologic dose in future trials.

Updates to the clinical program will appear in the National Library of Medicine's clinicaltrials.gov entry for Faridoxorubicin (AVA6000) under the trial designation, ID Number NCT04969835.

Christina Coughlin, CEO of Avacta Therapeutics commented,

"These two critical steps in the development of our faridoxorubicin (AVA6000) program and by extension the proprietary pre|CISION® platform demonstrate growing recognition by regulators of the safety of this platform.

"Highly favorable cardiac safety data for faridoxorubicin enable patients to be treated longer, as opposed to stopping the drug for a theoretical risk of cardiac toxicity which is the usual practice with doxorubicin therapy. Despite dosing to nearly 4x the standard dose of doxorubicin as well as to a higher lifetime maximum exposure, we have not seen a single case of severe cardiac toxicity.

Furthermore, identifying the path forward to the selection of the optimal biologic dose will enable a smooth transition to efficacy studies with faridoxorubicin program and allows the Company to implement these approaches in the platform currently in Phase 1b, facilitating the development across pre|CISION® medicines."

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About Avacta - https://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 payload delivery system based on a tumor-specific protease (fibroblast activation protein or FAP) that is designed to concentrate highly potent payloads 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.

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.

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