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Avacta Announces Promising Early Efficacy and Safety Data for AVA6000 in the Phase 1a Dose Escalation and Ongoing Enrollment in the Phase 1b Expansion Cohorts

Encouraging Progression Free Survival (PFS) data observed in patients with salivary gland cancers compared to conventional treatments

LONDON AND PHILADELPHIA - 07 March 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, is pleased to announce that the lead program of the Company, AVA6000, the first clinical stage asset which is a pre|CISION®-enabled form of doxorubicin, has completed the Phase 1a dose escalation with encouraging PFS data in patients with salivary gland cancers.

The Company has initiated enrollment in the Phase 1b expansion cohorts with multiple patients treated.

Promising early efficacy and safety signals are observed in the Phase 1a trial. As of the most recent data cut-off, the favorable safety profile continues to be observed when compared with conventional dose doxorubicin, including no observed events of severe cardiac toxicity, which are associated with conventional doxorubicin.

Among patients in the dose-escalation portion, 11 patients with salivary gland cancers have been treated with AVA6000 at or above the dose of 250 mg/m^2 and above. Among these 11 patients, one patient experienced a confirmed partial response as best response (greater than -30% reduction in tumor diameters by RECIST criteria), four patients had minor responses (-10 to -29% reduction by RECIST criteria), and only one patient had disease progression for a disease control rate of 91%. These responses have been durable to date. Importantly, the median PFS has not yet been reached, as five patients remain on AVA6000 treatment and 9 of the 11 patients are without progression and remain in follow-up. The median time of follow-up in this cohort is approximately 5 months. These data compare very favorably to published PFS reports (with conventional anti-cancer therapy) in this setting of pre-treated SGC, is reported at approximately 3.5 months. It is anticipated that PFS would be the primary endpoint in the registrational trial of AVA6000 in this indication, which is characterized by low response rates and high unmet need.

Avacta also announces patient dosing in the AVA6000 Phase 1b expansion cohorts with multiple patients treated in this portion of the trial, which include three indications: (1) salivary gland cancer, (2) triple negative breast cancer and (3) high grade soft tissue sarcoma. Each arm of the Phase 1b expansion cohort will enroll 20-30 patients by the following criteria.

- **Salivary gland cancers**: patients with advanced or metastatic salivary gland cancers of any histologic subtype. Patients may have received up to 1 prior line of therapy in the metastatic or advanced setting.
- **Triple negative breast cancer**: patients with advanced or metastatic triple negative breast cancer with up to 2 prior lines of therapy in the metastatic or advanced setting
- **High grade soft tissue sarcomas:** patients with undifferentiated pleomorphic sarcoma or dedifferentiated liposarcoma and patients may have received 0 or 1 prior line of therapy in the metastatic or advanced setting

The Company anticipates providing a further update from the Phase 1a dose escalation data in 2Q 2025 and Phase 1b dose expansion cohort data at the end of 2025. The full Phase 1a data will be presented in 2H 2025, including a full assessment of the cardiac safety data with long-term follow up. The data will allow the Company to plan for the registration study of AVA6000.

Alan Ho, MD PhD, Chief of the Head and Neck Oncology Service, Memorial Sloan Kettering Cancer Center and member, Avacta Scientific Advisory Board, commented:

"We are very excited to move the development of AVA6000 to the next level to generate data that demonstrates clinically meaningful efficacy and durability of response in patients with previously treated salivary gland cancers. It is important to note the high degree of unmet need in this disease where few agents have shown efficacy. I am happy to participate in the trials of AVA6000 in this disease setting going forward."

Christina Coughlin, CEO of Avacta Therapeutics commented:

"We are very pleased to advance to the expansion cohorts in the AVA6000 trial in these three indications with high unmet need. Our development of AVA6000 is proceeding according to plans and today's new data demonstrate the durability of the responses we have observed in the SGC indication. We believe that AVA6000 has an important role to play in the clinic, given our preliminary efficacy data and the large commercial market size of conventional doxorubicin"

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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 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.

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.