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Avacta Announces Positive New Data from the AVA6000 Phase 1 trial Demonstrating Clinically Meaningful Tumor Shrinkage in Patients with Salivary Gland Cancers

Meaningful tumor shrinkage observed in five out of 10 patients with partial and minor responses and 90% disease control rate in patients with salivary gland cancers

Phase 1b expansion cohorts screening patients in triple negative breast cancer, soft tissue sarcoma and salivary gland cancer

LONDON and PHILADELPHIA - January 16, 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 compelling new data in patients with salivary gland cancer (SGC) from the ongoing Phase 1a trial of AVA6000 in patients with FAP-positive solid tumors. The data demonstrates robust and meaningful tumor shrinkage in patients with salivary gland cancers, a disease with no standard therapy defined in the metastatic setting.

AVA6000 is the first peptide drug conjugate in Avacta's pipeline and consists of doxorubicin conjugated with Avacta's proprietary pre|CISION® peptide, that is specifically cleaved by fibroblast activation protein-alpha (FAP) in the tumor microenvironment.

The key findings include:

- Among 10 patients treated at the dose of 250 mg/m^2 and above, five patients demonstrate tumor shrinkage (one partial and four minor responses)
- Six of these 10 patients are continuing treatment and an additional two patients, who have reached maximum cycles, are still in follow up for progression free survival
- The safety profile of AVA6000 continues to demonstrate a robust reduction in severe hematologic and cardiac toxicities that are associated with conventional dose doxorubicin

Based on this favorable efficacy and safety data observed in the Phase 1a trial, Avacta has initiated three Phase 1b expansion cohorts in triple negative breast cancer, soft tissue sarcoma and salivary gland cancer in the first and second line setting. Patients are screening and the first patients to be treated in these expansions are expected imminently in the US.

Christina Coughlin MD, PhD, CEO of Avacta, commented,

"These data highlight the transformative potential of our pre|CISION® peptide drug conjugates in expanding the efficacy of highly potent therapeutics and support our growing optimism in this program.

"Salivary gland cancer is a devastating disease with no established standard of care treatment options. AVA6000 demonstrated a clinically meaningful tumor shrinkage in SGC patients, highlighting its potential as an important new treatment option for patients with SGC and other solid tumors.

"We look forward to continuing to work with our investigators and the broader community to explore its potential in SGC and other cancers. We are thrilled to begin enrollment in the expansion cohorts, and this part of the trial will also be conducted in less heavily pretreated patients which will allow us to better understand the potential of AVA6000 in these disease settings with high unmet need."

These results demonstrate preliminary evidence of durable antitumor activity in patients with SGC, supported by ongoing RECIST[1] responses (both partial and minor responses) in a disease setting with no standard of care. SGC accounts for 6-8% of head and neck cancers in the US, with approximately 2,500 cases diagnosed in the US each year[2]. There is no standard of care for SGC once patients have developed distant metastasis, with a five year survival rate of approximately 43%.

Clinical data observations:

Out of 10 patients with SGC treated at the dose of 250 mg/m^2 and above, 5 patients experienced clinically meaningful disease shrinkage, including a confirmed partial response (PR, 45% tumor shrinkage) and four minor responses (MR, 10-19.5% tumor shrinkage) using RECIST criteria.[1] These data include the following cases:

- A durable, confirmed PR was observed at 12 weeks in a 79-year-old male patient. The response is ongoing despite patient discontinuation due to reaching lifetime maximum of doxorubicin exposure. This patient

began their treatment with AVA6000 in October 2023 following one line of therapy which he experienced disease progression prior to enrolling in the AVA6000 clinical trial.

- Rapid and complete regression of large skin and visceral metastasis was observed in a 74-year-old male patient experiencing a MR, despite low to mid-level FAP expression in the cancer-associated fibroblasts alone. A 15% reduction in parotid and lymph nodal lesions continues at the12 weeks post scan. This patient began treatment in September 2024 following two prior lines of therapy to which he experienced disease progression with both therapies prior to enrolling in the AVA6000 trial.

Although these data are reported early in the treatment course of most patients, it is notable that six patients (of the 10 patients with SGC), including all five responders, remain on treatment and a further two patients remain in progression-free follow-up after having received the maximum number of cycles of AVA6000. Only one patient has reported disease progression as best response resulting in the disease control rate of 90% in this group of patients with salivary gland cancers.

Treatment with AVA6000 continues to be well-tolerated in both dosing arms, once every two weeks (Q2W) and once every three weeks (Q3W), with reduced hematologic and cardiac toxicities compared to conventional dose doxorubicin at 75 mg/m^2 dosed every 3 weeks. A maximum tolerated dose has not been identified in either arm of the trial.

[1] Reduction in the sum of longest diameters (SLD) is used to measure response per RECIST 1.1 with partial responses having at least a 30% reduction and minor responses of between >10% and <30% reduction.

[2] American Cancer Society: Key Statistics in Salivary Gland Cancers, www.cancer.org/cancer/types/salivary-gland-cancer.html.

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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.

About AVA6000: FAP-enabled doxorubicin

The lead pre|CISION® program AVA6000, a peptide drug conjugate form of doxorubicin, is in Phase 1 studies. It has shown an improvement in safety and tolerability in clinical trials to date compared with standard doxorubicin and preliminary signs of clinical activity in multiple patients.

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