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Avacta Group PLC
21 March 2024

This announcement contains inside information for the purposes of Article 7 of the UK version of Regulation (EU) No 596/2014 which is part of UK law by virtue of the European Union (Withdrawal) Act 2018, as amended ("MAR"). Upon the publication of this announcement via a Regulatory Information Service, this inside information is now considered to be in the public domain.

21 March 2024

Avacta Group plc

("Avacta" or the "Group" or the "Company")

Update on AVA6000 Phase 1a Clinical Trial Progress

Three patients now dosed in the US in two-weekly dose escalation study

Avacta receives approval to enrol patients in the UK in the ongoing two-weekly dose escalation study

Avacta Group plc (AIM: AVCT), a life sciences company developing innovative, targeted oncology drugs and powerful diagnostics, is pleased to announce that yesterday the third patient was dosed in the first cohort of the two-weekly Phase 1a dose escalation study of its lead pre|CISION™ drug AVA6000, a peptide drug conjugate designed to target the release of the chemotherapy doxorubicin to tumor tissue.

Many solid tumors have higher levels of an enzyme called fibroblast activation protein ("FAP") compared with healthy tissues. The pre|CISION™ technology is designed to render a chemotherapy inert until it encounters FAP. FAP targeted release of a chemotherapy aims to reduce damage to healthy tissues and systemic side effects, improve the tolerability for patients and thereby allow optimisation of the dosing schedule to improve efficacy.

The safety and tolerability of AVA6000 are continuing to be assessed in a Phase 1a dose escalation study. As announced on 13 December 2023, data to date from the three-weekly dosing arm of the trial demonstrated that the pre|CISION™ platform targets the release of the chemotherapy to the tumor as intended, that AVA6000 significantly improved the safety and tolerability of doxorubicin and that AVA6000 is already showing encouraging preliminary clinical signs of anti-tumor activity.

Cohort 7 was the final cohort in the three-weekly study and even at this dose level (385 mg/m^2), which is approximately 3.5x the equivalent standard dose of doxorubicin, dose-limiting toxicities were not observed and the Safety Data Monitoring Committee ("SMDC") has concluded that this dose level is safe. A number of patients remain on the three-weekly study at this time in several different cohorts.

Based on this very favourable three-weekly dosing safety profile, Avacta commenced a two-weekly dosing safety study in the US on the basis that this is likely to lead to better efficacy. Three patients have now been dosed in cohort 1 (160 mg/m^2) of the two-weekly dose escalation study in the US and Avacta has received regulatory and ethics approval to open sites in the UK in the two-weekly arm. Avacta anticipates that the SMDC will review the two-weekly cohort 1 data by the end of April.

The combined data from the three-weekly and two-weekly studies will provide information to allow the Company to define the dose and schedule to be used in future efficacy studies. Patients can be dosed in parallel in the two-weekly dose escalation study and Avacta remains on track to begin the dose expansion efficacy study in the second half of 2024. The data from the expansion study will be used to inform the optimal choice of a single orphan indication for the Phase 2 efficacy study which will follow on immediately.

Dr Alastair Smith, Chief Executive Officer of Avacta Group, commented:

"We are extremely pleased with the continued excellent progress of AVA6000 in the Phase 1a dose escalation study. These emerging data clearly demonstrate that the pre|CISION™ peptide drug conjugate platform is functioning in the way it was designed and is capable of targeting the release of a cancer therapy to the tumor. Targeted therapy that spares healthy tissues is a holy grail of oncology drug development and we believe we have a unique platform to target FAP-rich tumor tissues to deliver significantly better outcomes for patients and substantial value to our shareholders.

"The continuing validation of the pre|CISION™ platform we are seeing in the clinic underlines our confidence in the significant opportunity to apply pre|CISION™ to a range of warheads, including those much more potent than doxorubicin.

We are now in a very strong position to deliver significant clinical and commercial milestones relating to AVA6000 and the wider pre|CISION™ platform, and we are looking forward to providing a further detailed update on the clinical trial at the American Association for Cancer Research meeting in April."

Lee Cranmer MD, PhD, FACP, Curtis and Elizabeth Anderson Endowed Professor in Sarcoma Research, University of Washington and Professor and Director of Sarcoma Oncology, Fred Hutchinson Cancer Center, commented:

"I am encouraged by the initial data with AVA6000 in the Phase 1 trial and look forward to working with my fellow investigators and our collaborators at Avacta to understand better the optimal dosing for this novel approach to targeted cancer therapy."

-Ends-

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About Avacta Group plc - https://www.avacta.com

Avacta Group is a UK-based company focused on improving healthcare outcomes through targeted cancer treatments and diagnostics.

Avacta has two divisions: an oncology biotech division harnessing proprietary therapeutic platforms to develop novel, highly targeted cancer drugs, and a diagnostics division, focused on supporting healthcare professionals and broadening access to testing. Avacta's two proprietary platforms, Affimer® and pre|CISION™ underpin its cancer therapeutics whilst the diagnostics division leverages the Affimer® platform to drive competitive advantage in its markets.

The pre|CISION™ platform modifies chemotherapy to be activated only in the tumor tissue, reducing systemic exposure and toxicity. This is achieved by harnessing an enzyme called FAP which is highly upregulated in most solid tumors compared with healthy tissues, turning chemotherapy into a "precision medicine". The lead pre|CISION™ programme, AVA6000 a tumour activated form of doxorubicin, is in Phase 1 studies and has shown dramatic improvement in safety compared with standard doxorubicin, and early signs of clinical activity.

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