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Avacta Group PLC
23 May 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.

23 May 2024

Avacta Group plc

("Avacta" or the "Company")

Successful Completion of First Cohort and Dosing of Three Patients of the Second Cohort in Arm 2 of Avacta's AVA6000 Phase 1 trial

Initiation of FAPI-PET Sub-study in the AVA6000 Phase 1 trial

- *First cohort successfully completed in Arm 2 with no adverse safety signals and initiation of FAPI-PET sub-study to better characterize the FAP-positive disease burden at the time of study entry in selected patients*
- *Two-weekly dosing study for AVA6000, Avacta's peptide drug conjugate, is designed to potentially optimise efficacy and maintain the robust safety profile of AVA6000*
- *The Company remains on track for stated goals in 2H 2024*

Avacta Group plc (AIM: AVCT), a life sciences company developing innovative, targeted oncology drugs and powerful diagnostics, is pleased to announce the successful completion of the first cohort and dosing of 3 patients in the second cohort in the dose escalation study of Arm 2 of its Phase 1 trial for AVA6000, a peptide drug conjugate form of doxorubicin chemotherapy. In addition, a sub-study utilizing FAPI-PET scanning at baseline has also commenced to further characterize the full burden of FAP-positive disease in patients.

The Phase 1 trial is evaluating the safety and tolerability of AVA6000, Avacta's lead programme, leveraging its proprietary pre|CISION™ technology. Arm 2 of the trial, which follows positive data from Arm 1, is designed to optimise the schedule and dose for efficacy studies following the successful completion of Arm 1 and will follow a two-weekly dosing schedule ("Q2W").

Dosing of the second cohort in Arm 2 has now commenced, with three patients successfully dosed. The sub-study through partnership with SOFIE utilising baseline [^{18}F]FAPI-74 PET scanning in the AVA6000 Phase 1 trial has commenced and is designed to better characterise in a subset of patients the whole-body tumor expression of the target of the pre|CISION™ molecule and levels of fibroblast activation protein ("FAP") expression, an enzyme present in high concentrations in many solid tumors. These data will inform on various indications for further efficacy studies. This sub-study represents an ongoing collaboration between Avacta and SOFIE, in the use of [^{18}F]FAPI-74 PET as a complementary diagnostic. [^{18}F]FAPI-74 PET is currently in clinical development and for investigational use only.

Avacta is on track for stated goals in the second half of 2024, including the commencement of the dose expansion Phase 1b efficacy study and presenting further data from the AVA6000 trial. The data from this expansion study will be used to inform the optimal choice of a single indication for a Phase 2 efficacy study which will follow the expansions.

Christina Coughlin MD, PhD, Chief Executive Officer of Avacta, commented: *"We're delighted to be progressing the two weekly dosing schedule arm of the Phase 1 trial of AVA6000. This is an important milestone which supports our continued confidence in AVA6000 and in the wider pre|CISION™ platform. The introduction of a new diagnostic approach of [^{18}F]FAPI-74 -PET scanning into the programme will help to better characterize the FAP expression among patients, potentially assisting in indication selection.*

"We're excited to be working with our investigators to integrate these tools to accelerate our efforts to optimise indications, dosing and schedule, as we bring this promising program through clinical studies."

Phase 1a Arm 1

Seven dose cohorts (n=42) were completed in the Phase 1a Arm 1 of the trial with a dosing schedule of every three weeks ("Q3W").

Data from Arm 1 of the trial, presented at the American Association for Cancer Research (AACR) meeting in April, demonstrated that AVA6000 delivers high concentrations of doxorubicin to the tumor microenvironment ("TME") relative to plasma, resulting in significant antitumor activity in patients whose tumors have over-expression of FAP.

A significant reduction in the frequency and severity of the known doxorubicin toxicities was observed across the dosing

range in Arm 1. A maximum tolerated dose has not been reached in the three-weekly dose escalation study despite dosing approximately 3.5x the normal level of doxorubicin in the highest and final dose cohort in Arm 1 of the Phase 1a study.

-Ends-

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About AVA6000

AVA6000, Avacta Therapeutics' lead oncology programme, is a peptide drug conjugate consisting of doxorubicin conjugated with a peptide moiety that is specifically cleaved by fibroblast activation protein (FAP) in the tumor microenvironment (TME).FAP is selectively overexpressed in many solid tumors. The peptide moiety (pre|CISIONTM) prevents cellular entry of doxorubicin unless cleaved by FAP, thus enabling targeted delivery of doxorubicin directly to the TME.

About SOFIE Biosciences (SOFIE)

SOFIE's vision is to improve patient outcomes by developing and delivering molecular diagnostics and therapeutics (theranostics). With its robust radiopharmaceutical production and distribution network, mature contract manufacturing services and high value theranostic intellectual property, SOFIE is poised to deliver on the promise of radiopharmaceuticals. For more information visit our website, https://sofie.com/ or contact us by email at info@sofie.com

About Avacta Group plc - www.avacta.com

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

Avacta Therapeutics is a clinical stage oncology biotech division harnessing proprietary therapeutic platforms to develop novel, highly targeted cancer drugs.

Avacta Diagnostics focuses on supporting healthcare professionals and broadening access to diagnostics.

Avacta has two proprietary platforms, pre|CISION™ and Affimer®.

The pre|CISION™ platform is a highly specific substrate for fibroblast activation protein (FAP) which is upregulated in most solid tumor compared with healthy tissues. The pre|CISION™ platform harnesses this tumor specific protease to activate pre|CISION™ peptide drug conjugates and pre|CISION™ antibody/Affimer® drug conjugates in the tumor microenvironment, reducing systemic exposure and toxicity, allowing dosing to be optimised to deliver the best outcomes for patients.

The lead pre|CISION™ programme AVA6000, a peptide drug conjugate form of doxorubicin, is in Phase 1 studies. It has shown a dramatic 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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