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Antisoma to amend ACCEDE phase III study of AS1413

London, UK, and Cambridge, MA: 08 October 2009 Antisoma announces that, following discussions with FDA and trial investigators, it plans to amend the primary endpoint in the ACCEDE study of AS1413. The ACCEDE study is an ongoing randomised, controlled phase III trial that compares AS1413 plus cytarabine with daunorubicin plus cytarabine in patients newly diagnosed with secondary acute myeloid leukaemia (secondary AML).

The primary endpoint of the trial will continue to be based on remission rate, defined as the proportion of patients who achieve complete remission (CR) or complete remission with incomplete blood count recovery (CRI). However, the requirement for confirmation of remission before further intervention will be removed. The revised primary endpoint will therefore be initial remission rate rather than confirmed remission rate. Confirmed remission rate will become a secondary endpoint, alongside duration of remission and overall survival.

The primary endpoint is being changed because a number of trial investigators considered it inappropriate to perform additional bone marrow sampling to confirm CR or CRI before instigating post-remission therapy. Where patients were proceeding rapidly to post-remission therapy, the need to confirm remission meant a second invasive procedure was required within days of the initial test for remission. FDA has recognised that trends in medical practice mean post-remission therapy is now often started shortly after the initial achievement of remission.

Antisoma's decision to change the primary endpoint will mean that the ACCEDE study is no longer covered by a Special Protocol Assessment (SPA). FDA has confirmed, however, that the amendment will have no impact on whether a New Drug Application (NDA) based on results from ACCEDE would be accepted for filing.

Commenting on this development, Dr Robert Stuart of the Medical University of South Carolina, an investigator in the ACCEDE trial, said: "This amendment brings the AS1413 trial in line with current medical practice for treatment of AML and reduces the need to conduct additional invasive tests. It will therefore be welcomed by investigators and patients. The ACCEDE study is an important and rigorous evaluation of a novel agent for AML patients who don't benefit much from currently available drugs."

Dr Ursula Ney, Chief Operating Officer of Antisoma, said: "The ACCEDE study is the first large, randomised trial to be conducted in patients with secondary AML. It will provide comparative data on both remission rates and longer term outcomes in patients receiving AS1413 or standard therapy. Our planned amendment is designed to ensure that we deliver a well-powered study as well as the range of data needed to fully capture any benefit provided by AS1413. We believe this will put us in the best position to generate successful marketing applications if the data are positive."

Enrolment into the ACCEDE study is on track, with approximately one third of the target of 450 patients now recruited. Key data, including those critical for regulatory filings, are expected to be available in late 2010 or early 2011.

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Notes

About the AS1413 ACCEDE study

The ACCEDE (AS1413 (Amonafide) Cytarabine Combination: Evaluating Drug Efficacy) study is a 450-patient randomised controlled trial that compares AS1413 plus cytarabine with daunorubicin plus cytarabine in patients with secondary AML (secondary acute myeloid leukaemia). This is a form of AML that evolves from myelodysplastic syndromes or develops following treatment of other cancers with radiotherapy or chemotherapy. The study is enrolling patients in the US, Europe, Asia, Latin America and Australia.

About AML

AML is a type of cancer in which the bone marrow makes abnormal and immature blood cells, eventually leading to bone marrow failure. The American Cancer Society estimates that there will be over 13 000 new cases of AML

diagnosed this year in the US alone.

About AS1413

AS1413 (amonafide L-malate) was added to Antisoma's pipeline through the acquisition of Xanthus Pharmaceuticals, Inc. in June 2008. AS1413 is a DNA intercalator that induces apoptotic signalling by blocking Topoisomerase II binding to DNA. This differs from the action of classical Topoisomerase II inhibitors, which induce apoptosis by causing extensive DNA damage. A further distinctive feature of AS1413 is its ability to evade Pgp and related transporters responsible for multi-drug resistance (MDR). A pivotal phase III trial is evaluating AS1413 as a treatment for secondary AML. Patients with secondary AML often have multi-drug resistant disease. Antisoma is developing AS1413 independently and plans to commercialise the drug itself in the US while seeking partnerships for commercialisation in other territories.

About Antisoma

Antisoma is a London Stock Exchange-listed biopharmaceutical company that develops novel products for the treatment of cancer. The Company has operations in the UK and the US. Please visit www.antisoma.com for further information about Antisoma.

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