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Phase III trial of ASA404 in lung cancer completes patient enrolment

1 September 2009, London, UK, and Cambridge, MA: Antisoma plc (LSE: ASM; USOTC: ATSMY) today announces that the ATTRACT-1 phase III trial of ASA404 in non-small cell lung cancer (NSCLC) has reached its enrolment target of 1,200 patients. The trial is the single pivotal registration study for the drug as a first-line treatment for squamous and non-squamous NSCLC, and is being conducted by Novartis, Antisoma's development and commercialisation partner for ASA404.

Glyn Edwards, Antisoma's CEO, said: "Novartis has done an excellent job in rapidly completing recruitment into this very large trial of ASA404 in lung cancer. We can now be even more confident that the results will be available in time to support potential marketing applications in 2011."

Primo N. Lara, Professor of Medicine at the University of California Davis Cancer Center and U.S. Steering Committee Chair for the ATTRACT-1 study, said: "Lung cancer afflicts an enormous number of patients worldwide and there is a clear need for new and improved treatment options. Phase II trials reported substantial benefits for lung cancer patients receiving ASA404, and I therefore look forward greatly to seeing the results of this large and important phase III trial."

ASA404 is a Tumour-Vascular Disrupting Agent (Tumour-VDA) that selectively disrupts established tumour vasculature, inhibits tumour blood flow, and causes extensive tumour necrosis.

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About the ATTRACT-1 study

ATTRACT-1 is a pivotal study designed to support applications to market ASA404 in previously untreated, advanced NSCLC. It is a randomised, double-blind, placebo-controlled, multicentre phase III trial being conducted across the US, EU, Japan and other territories. ATTRACT-1 opened in April 2008 and has enrolled patients with all histologies, or types, of NSCLC, including squamous and non-squamous cancers. Patients have been randomised 1:1 to receive either ASA404 plus chemotherapy (carboplatin/paclitaxel) or a placebo plus chemotherapy (carboplatin/paclitaxel) as a control.

The primary endpoint of ATTRACT-1 is overall survival. Key secondary endpoints are survival in the squamous and non-squamous patient subgroups. An interim look is expected to be triggered before the end of 2009. Following collation and processing of data, the interim look will take place in early 2010. The outcome will be announced immediately. The most likely outcome is that the study will continue to completion. No data will be released unless the look indicates that the trial should stop because of clear futility or early evidence of overwhelming efficacy. Full and final data are expected to be available in late 2010 or early 2011, in time to support potential applications to market the drug in 2011.

In addition to the ATTRACT-1 trial in previously untreated NSCLC patients, Novartis is conducting a separate pivotal study, ATTRACT-2, to evaluate ASA404 in NSCLC patients who have received one previous treatment.

About non-small cell lung cancer (NSCLC)

Lung cancer is the biggest cause of cancer death for both men and women worldwide, with 1.2 million new cases per year and around 920,000 deaths. Around 85-90% of all lung cancer cases are NSCLC.

About ASA404

ASA404 (vadimezan, formerly known as DMXAA and AS1404) is a small-molecule Tumour-Vascular Disrupting Agent (Tumour-VDA) which targets the blood vessels that nourish tumours. The drug was discovered by Professors Bruce Baguley and William Denny and their teams at the Auckland Cancer Society Research Centre, University of Auckland, New Zealand. It was in-licensed by Antisoma from Cancer Research Ventures Limited (now Cancer Research Technology), the development and commercialisation company of the Cancer Research Campaign (now Cancer Research UK) in 2001. Worldwide rights to the drug were licensed to Novartis AG in April 2007. Antisoma has an

option to co-sell ASA404 with Novartis in the United States. Novartis is conducting phase III studies of ASA404 in NSCLC, and also plans to investigate the drug's potential as a treatment for metastatic breast cancer.

A randomised phase II trial in patients receiving first-line treatment for NSCLC showed that addition of ASA404 to carboplatin and paclitaxel chemotherapy improved survival by 5 months. A second, single-arm, phase II trial also reported positive results with ASA404 in the same patient group.

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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