

21/05/2009

Phase II trial of ASA404 published in *Lung Cancer*

London, UK, and Cambridge, MA: 21 May 2009 – Antisoma plc (LSE: ASM; USOTC: ATSMY) announces that the journal *Lung Cancer* has published the results of a single-arm phase II trial of ASA404 in non-small cell lung cancer (NSCLC). The trial included patients with both major histological forms of NSCLC: squamous and non-squamous. Positive data from this trial supported the progress of ASA404 into phase III trials in patients with NSCLC of all histologies.

ASA404 is a Tumour-Vascular Disrupting Agent (Tumour-VDA) that destroys tumours by selectively collapsing the tumour blood vessels on which they depend to survive and grow. A randomised phase II trial of ASA404 in patients with previously untreated, advanced NSCLC was published recently in the *British Journal of Cancer*. In that trial, addition of ASA404 at 1200 mg/m² to standard chemotherapy was generally well tolerated in both squamous and non-squamous patients. The combination of ASA404 and chemotherapy produced a median survival of 14.0 months compared with 8.8 months in patients receiving chemotherapy alone.

In the newly published trial, a further 30 similar patients with NSCLC received standard chemotherapy plus ASA404 at a higher dose of 1800 mg/m². Median survival was 14.9 months, corroborating the findings from the randomised study. Favourable efficacy findings together with the acceptable safety profile seen in this study led to the selection of the 1800 mg/m² dose for phase III studies of ASA404 in NSCLC.

Two phase III trials are currently being conducted by Novartis, with whom Antisoma signed a worldwide development and commercialisation deal for ASA404 in April 2007: ATTRACT-1 is evaluating ASA404 in previously untreated NSCLC patients, while ATTRACT-2 is testing ASA404 in patients who have received a previous round of treatment with other drugs.

Enquiries:

Glyn Edwards, CEO Daniel Elger, VP, Marketing & Communications Antisoma plc	+44 (0)7909 915 068
Mark Court/Lisa Baderoon/Rebecca Skye Dietrich Buchanan Communications	+44 (0)20 7466 5000
Seth Lewis The Trout Group	+1 617 583 1308

Except for the historical information presented, certain matters discussed in this announcement are forward looking statements that are subject to a number of risks and uncertainties that could cause actual results to differ materially from results, performance or achievements expressed or implied by such statements. These risks and uncertainties may be associated with product discovery and development, including statements regarding the company's clinical development programmes, the expected timing of clinical trials and regulatory filings. Such statements are based on management's current expectations, but actual results may differ materially.

Notes for Editors:

About the single-arm phase II trial of ASA404 1800 mg/m² in NSCLC

This was a single-arm trial that enrolled patients receiving first-line chemotherapy treatment for stage IIIb or IV NSCLC. Thirty patients received up to 6 cycles of standard therapy (carboplatin AUC 6 mg/mL*min and paclitaxel 175 mg/m²) plus ASA404 1800 mg/m². The trial was conducted at hospitals in New Zealand, Germany and Australia that had also participated in a previous randomised, controlled study comparing standard therapy plus ASA404 1200 mg/m² with standard therapy alone.

Key results reported in the *Lung Cancer* publication are as follows:

Tumour response rate by independent assessment was 37.9%. In the previous randomised study, response rates were 31.3% in the ASA404 1200 group (ASA404 1200mg/m² plus standard chemotherapy) and 22.2% in the standard therapy group (standard chemotherapy alone, as detailed above).

Median time to tumour progression (TTP) was 5.5 months by investigator assessment. In the previous randomised study, TTP was 5.4 months in the ASA404 1200 group and 4.4 months in the standard therapy group.

Median survival was 14.9 months. In the previous randomised study, median survival times were 14.0 months in the ASA404 1200 group and 8.8 months in the standard therapy group.

Addition of ASA404 1800 mg/m² to chemotherapy was generally well tolerated. As in the previous randomised study, there was no evidence for a difference in safety profile between patients with squamous and non-squamous histology.

The reference for the paper, which is in press and has been e-published ahead of printing, is: McKeage MJ, *et al.* Phase II study of ASA404 (vadimezan, 5,6-dimethylxanthenone-4-acetic acid/DMXAA) 1800 mg/m² combined with carboplatin and paclitaxel in previously untreated advanced non-small cell lung cancer. *Lung Cancer* 2009, doi: 10.1016/j.lungcan.2009.03.027

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 August 2001. Worldwide rights to the drug were licensed to Novartis AG in April 2007. In addition to ongoing phase III studies in NSCLC, Novartis recently decided to extend investigation of ASA404 to patients with metastatic breast cancer.

About 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 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.

- END -

[^ Back to top](#)

[centre](#) | [Media centre](#) | [Partnering](#) | [Careers](#) | [Contact us](#) | [Site map](#) | [Alert service](#) | [Disclaimer](#) | [Accessibility](#)