Press releases

30/05/2008

Antisoma announces positive ASA404 presentations at ASCO

London, UK, 30 May 2008 – Antisoma (LSE:ASM; USOTC:ATSMY) announces today details of two presentations on ASA404 that will be made at the upcoming 2008 Annual Meeting of the American Society of Clinical Oncology (ASCO):

Abstract no. 8072 (poster) *Comparison of safety and efficacy between squamous and non-squamous non-small cell lung cancer (NSCLC) patients in phase II studies of DMXAA (ASA404)*; M. J. McKeage, M. B. Jameson, AS1404-201 Study Group Investigators; on Sunday 1 June, 2-6pm - Board 45c, in S Hall A1.

Abstract no. 5007 (oral presentation) *Addition of DMXAA (ASA404) to docetaxel in patients with hormone-refractory metastatic prostate cancer (HRMPC): update from a randomized, phase II study*; R. Pili, M. Rosenthal, AS1404-203 study group investigators; on Monday 2 June, 11.30-11.45am in Clinical Science Symposium on 'Novel antiangiogenic mechanisms' in Room W375a.

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Except for the historical information presented, certain matters discussed in this statement 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.

Background on ASA404
ASA404 (DMXAA) 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. A phase III trial (ATTRACT-1) is evaluating ASA404 in combination with carboplatin and paclitaxel in the first-line treatment of non-small cell lung cancer.

Background on Antisoma
Headquartered in London, UK, Antisoma is a biopharmaceutical company that develops novel products for the treatment of cancer. Antisoma fills its development pipeline by acquiring promising new product candidates from internationally recognised academic or cancer research institutions. Its core activity is the preclinical and clinical development of these drug candidates. Please visit www.antisoma.com for further information about Antisoma.

Press releases

01/06/2008

Positive data on Antisoma's ASA404 presented at ASCO

London, UK, and Chicago, IL, 1 June 2008 – Antisoma (LSE:ASM; USOTC:ATSMY) announces that two presentations supporting ASA404 are being made at this year's American Society of Clinical Oncology (ASCO) meeting in Chicago. ASA404 is a Tumour-Vascular Disrupting Agent for which worldwide rights were licensed to Novartis in April 2007.

Broad potential in lung cancer

A poster presentation to be given today shows that patients with both squamous and non-squamous types of non-small cell lung cancer experienced a survival benefit in phase II trials with ASA404. Addition of ASA404 to chemotherapy was generally well tolerated in both groups, with no evidence for bleeding related side-effects that have been seen with some other drugs in squamous patients. Around 30% of patients with non-small cell lung cancer have squamous disease.

The ASCO presentation is a retrospective analysis of data from phase II trials in which ASA404 was added to carboplatin and paclitaxel chemotherapy. Patients who received two different doses of ASA404 with their chemotherapy were pooled and compared with patients who received chemotherapy alone. Median survival data showed an extension of 4.7 months in squamous patients (10.2 vs 5.5 months) and of 3.9 months in non-squamous patients (14.9 vs 11.0 months). Response rates and time to tumour progression were also superior in both groups with ASA404.

The data will be presented by Dr Mark McKeage of the Auckland Cancer Centre, New Zealand, a leading investigator in phase II trials of ASA404 who is now participating in Novartis' ATTRACT-1 phase III trial of ASA404 in non-small cell lung cancer. Dr McKeage said "These data suggest that ASA404 could provide benefits for a wide range of lung cancer patients and support the broad inclusion criteria of the phase III ATTRACT-1 study."

The ATTRACT-1 phase III trial started in April 2008 and includes both squamous and non-squamous patients. Patients are being randomised to receive carboplatin and paclitaxel plus either ASA404 or a placebo. The primary endpoint in the trial is overall survival, and key secondary endpoints are overall survival in the squamous and non-squamous subgroups. If the ATTRACT-1 trial yields positive results, it is expected that filings for marketing authorisations will take place in 2011.

Glyn Edwards, CEO of Antisoma, added: "The phase II trial data in lung cancer have provided remarkably consistent support for ASA404 across different measures of efficacy, with different doses, and now in patients with different types of the disease."

The poster presentation will be available from 8pm today UK time (2pm Chicago time) on Antisoma's website (www.antisoma.com).

Supportive interim data in prostate cancer

An oral presentation on ASA404 will be given tomorrow in the Clinical Science Symposium 'Novel anti-angiogenic mechanisms' by Prof Roberto Pili of Johns Hopkins University. This presentation will include details of interim findings from the phase II trial of ASA404 in prostate cancer, which were announced in headline form in October, as well as a new analysis of ASA404's effects on the prostate cancer biomarker PSA.

In the prostate cancer trial, patients were randomised to receive either 1200 mg/m^2 ASA404 plus docetaxel or docetaxel alone. Several different measures now suggest better results with the ASA404-docetaxel combination than with docetaxel alone:

- PSA response rates were 59% with ASA404 plus docetaxel and 37% with docetaxel alone. A new analysis considers the proportion of patients showing a 30% decline in PSA levels in the 3 months after the start of treatment. This was the PSA measure most predictive of survival in a major prostate cancer study. Proportions of patients with such a PSA decline were 63% with ASA404 plus docetaxel and 47% with docetaxel alone
- Tumour response rates in patients assessable by RECIST were 23% in patients who received ASA404 plus docetaxel versus 9% in patients who received docetaxel alone
- Time to disease progression was 7.3 months in patients who received ASA404 plus docetaxel and 6.9 months in patients who received docetaxel alone, according to investigators' assessment; an independent assessment showed a similar pattern (8.7 vs 8.4 months)
- Safety findings from the trial showed that addition of ASA404 to chemotherapy was generally well tolerated.

Overall, interim findings from the trial are encouraging. A decision on next steps in prostate cancer will be made once median survival data are available. These are expected during the second half of this year.

Prof Pili's presentation will be available from 5.30pm UK time tomorrow (11.30am Chicago time) on Antisoma's website at www.antisoma.com

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Notes for Editors:

PSA and PSA responses
PSA is a protein, prostate-specific antigen. Levels of PSA in the blood are used in the diagnosis of prostate cancer and the tracking of responses to its treatment. PSA is one of the most widely recognised disease markers in oncology. In the ASA404 phase II trial, PSA response was defined as a 50% or greater reduction in PSA level from baseline. This is in accordance with the Bubley criteria (*Eligibility and response guidelines for phase II clinical trials in androgen-independent prostate cancer: recommendations from the Prostate-Specific Antigen Working Group. Journal of Clinical Oncology* 1999, 17:3461-3467).

Data supporting the importance of a 30% decline in PSA within three months of the start of treatment are reported in *'Prostate-Specific Antigen and Pain Surrogacy Analysis in Metastatic Hormone-Refractory Prostate Cancer'*; Andrew J. Armstrong, Elizabeth Garrett-Mayer, Yi-Chun Ou Yang, Michael A. Carducci, Ian Tannock, Ronald de Wit, and Mario Eisenberger; *Journal of Clinical Oncology* 2007, 25:3965-3970.

RECIST
Tumour responses (reflecting the growth or shrinkage or tumours after treatment) are often assessed according to RECIST (Response Evaluation Criteria In Solid Tumours). In prostate cancer, modified RECIST criteria are used because of the need to assess bone metastases, which cannot be assessed using the standard criteria.

Time to tumour/time to disease progression
Time to tumour progression is the time from the start of treatment (of a solid tumour) until disease progression is shown according to RECIST. As with the evaluation of response, this assessment is modified in prostate cancer. In the phase II ASA404 prostate cancer trial, investigators' assessment of time to disease progression included RECIST data, PSA data and clinical observations. Independent assessment of time to disease progression used RECIST and PSA data.

Background on ASA404
ASA404 (DMXAA) 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. Antisoma has conducted a number of phase II trials, including a randomised trial in non-small cell lung cancer. In this trial, patients who received ASA404 in addition to chemotherapy had a median survival of 14.0 months while patients who received chemotherapy alone had a median survival of 8.8 months. Additional details of phase II findings are available on Antisoma's website at www.antisoma.com. Worldwide rights to ASA404 were licensed to Novartis AG in April 2007. A phase III trial (ATTRACT-1) is evaluating ASA404 in combination with carboplatin and paclitaxel in the first-line treatment of non-small cell lung cancer.

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