

Press releases

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AS1411 shows activity in kidney cancer but AML remains priority

London, UK, and Cambridge, MA: 16 December 2009 - Antisoma plc (LSE: ASM; USOTC: ATSMY) announces that results of its phase II trial of AS1411 as a second-line treatment for metastatic renal cell carcinoma (RCC; kidney cancer) provide further evidence that the drug has anti-cancer activity. Safety findings suggest that AS1411 is exceptionally well tolerated compared to most current cancer treatments. Data from the trial will be submitted to a forthcoming scientific meeting.

Antisoma had two aims for this study. One was to decide whether to continue development in RCC; the second was to inform development in other cancer settings.

With respect to RCC, the AS1411 phase II data have been evaluated in the context of findings from a recent phase III study of the new drug everolimus, which was conducted in a very similar patient population. Independent assessment of scans from the AS1411 trial suggests single-agent activity comparable with that of everolimus, although the median progression-free survival was slightly inferior. Given the approval of everolimus earlier this year and the many other drugs now available for RCC, Antisoma does not plan to pursue development of AS1411 in this setting.

With respect to broader development, the AS1411 phase II trial in RCC provides further evidence of anti-cancer activity and a highly favourable safety profile. These observations support previous findings suggesting that AS1411 has potential in various cancers. For the immediate future, development will remain focused in AML (acute myeloid leukaemia). A randomised phase II trial in this setting reported positive data earlier this year, and a phase IIb trial in AML will begin soon.

Glyn Edwards, CEO of Antisoma, said: "We have taken a critical look at the renal cancer market and decided not to pursue development of AS1411 for this indication. We are, however, very encouraged to see further evidence of activity with AS1411, and are now focusing our efforts around this drug on the forthcoming trial in AML, a setting where we have already reported positive data from a randomised phase II trial."

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About the AS1411 phase II trial

Patients in the study had metastatic renal cell carcinoma that had previously been treated with at least one tyrosine kinase inhibitor (sunitinib or sorafenib). Thirty-five patients were enrolled at centres in the US. All received monotherapy treatment with AS1411 at 40mg/kg/day for 4 days of continuous infusion over one or two cycles. Response rates and progression-free survival were assessed using tumour scans, and safety and pharmacokinetic data were collected.

About AS1411

AS1411 belongs to a new type of drug called aptamers. These drugs are short pieces of DNA or RNA that fold into three-dimensional structures capable of targeting particular proteins. AS1411 is a DNA aptamer that targets nucleolin, a protein found on the surface of cancer cells.

AS1411 was originally developed by Dr Paula Bates, Dr John Trent and Prof. Donald Miller at the University of Alabama and then at the University of Louisville. Antisoma added AS1411 to its pipeline when it acquired the Louisville-based company Aptamera Inc. in 2005.

In May 2009, Antisoma reported positive findings from a randomised phase II trial in which AS1411 was given in combination with high-dose cytarabine to patients with relapsed and refractory AML (acute myeloid leukaemia). A phase IIb trial in AML is expected to start in early 2010.

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. It has two drugs in phase III trials: ASA404, a tumour-vascular disrupting agent, which is partnered with Novartis and which is under development for lung and breast cancers; and AS1413, a novel DNA intercalator being evaluated in secondary AML. Please visit www.antisoma.com for further information about Antisoma.