

**ASH presentation highlights durable responses with Antisoma's AS1413 in secondary AML**

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Cancer drug developer Antisoma plc (LSE: ASM; USOTC: ATSMY) announces that new data showing durable responses in patients treated with its novel chemotherapy drug AS1413 were presented yesterday at the American Society of Hematology (ASH) meeting in San Francisco. These findings result from extended follow-up of patients in a large phase II trial, in which AS1413 was administered together with cytarabine as a first-line treatment for secondary acute myeloid leukaemia (secondary AML). They were presented by trial investigator Dr Steven Allen of North Shore University Hospital, Albert Einstein College of Medicine, Manhasset, New York, and provide further support for the ongoing phase III trial evaluating AS1413 in secondary AML.

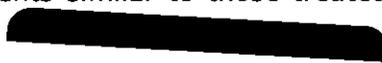
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Of 88 patients in the phase II trial, 42.0% (37 patients) responded to treatment and entered remission, with 38.6% (34 patients) showing a complete response to the AS1413 plus cytarabine regimen. This clearly exceeds published complete response rates of 24% and 26% achieved in similar secondary AML patients with the current standard treatment of daunorubicin plus cytarabine. The latest findings indicate that many of the responses seen with AS1413 were durable. Kaplan-Meier analyses show that 18 months after treatment 40% of responders remained in remission and 43% of responders were still alive.

Secondary AML is a form of leukaemia that evolves from a prior myelodysplastic syndrome or develops following radiotherapy or chemotherapy treatment for other cancers. Patients generally have a poor prognosis and often show 'multi-drug resistance,' with cancer cells that are unresponsive to various treatments. An important property of AS1413 is its ability to evade multi-drug resistance mechanisms, notably the 'P-glycoprotein pump' that extrudes chemotherapy drugs from cancer cells. In the AS1413 phase II trial, leukaemia cells from 15 patients were tested to see whether they accumulated or extruded AS1413 and daunorubicin. AS1413 was retained to a significantly greater extent than daunorubicin. This could explain the durable responses observed in the phase II trial as well as the superior response rate seen in this trial with AS1413 plus cytarabine compared to previous trials that tested daunorubicin plus cytarabine in secondary AML.

Commenting on the data, trial investigator Dr Harry P. Erba, Associate Professor of Internal Medicine at the University of Michigan Health System, said: "Patients with secondary AML have a very poor prognosis. In this study, most patients were over 60 and almost half had leukaemic cell karyotypes associated with unfavourable outcomes. Despite these adverse prognostic factors, we observed a 42% response rate and we now see that a significant fraction of the responses are durable. AS1413 combined with cytarabine appears to be a promising therapy for patients with secondary AML."

AS1413 is currently being tested in a 450-patient pivotal phase III trial under a Special Protocol Assessment (SPA) agreed with the US Food and Drug Administration (FDA). The phase III trial compares AS1413 plus cytarabine to daunorubicin plus cytarabine in patients similar to those treated in the phase II trial.



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Glyn Edwards, Antisoma's CEO said: "The latest update from the phase II trial reinforces our view that AS1413 is a drug with unique potential based on distinctive features that could translate into significant benefits for patients. We are making good progress with the phase III study in secondary AML and believe that AS1413 could ultimately find application in a number of blood cancer settings."

A copy of the poster presented at the ASH meeting is available on the Antisoma website at [www.antisoma.com](http://www.antisoma.com).

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**About AS1413**

AS1413 (amonafile; formerly also known as 'Xanafide') is in phase III development for the blood cancer secondary AML. The drug 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). Patients with secondary AML often have multi-drug resistant disease.

**References**

Earlier data from the AS1413 phase II trial in secondary AML were reported at the ASCO 2007 and 2008 meetings (2008 poster is available at [www.antisoma.com](http://www.antisoma.com)). Data on drug efflux from the leukaemia cells of patients in the phase II trial of AS1413 were reported in an abstract to ASCO 2008 (Lundberg *et al.*). The two studies referred to in this release that reported on response rates with daunorubicin plus cytarabine in secondary AML were SWOG 9031 (Leith *et al.*, *Blood* 1999; 94: 1086-99) and SWOG 9333 (Anderson *et al.*, *Blood* 2002; 100: 3869-76).

**About AML (acute myeloid leukaemia) and secondary AML**

AML is a type of cancer in which the bone marrow makes abnormal and immature blood cells, eventually leading to bone marrow failure. Secondary AML is a form of the disease that evolves from a prior myelodysplastic syndrome or develops following radiotherapy or chemotherapy treatment for other cancers.

**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](http://www.antisoma.com) for further information about Antisoma.

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