

Press releases

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Antisoma receives FDA approval for oral fludarabine, plans commercialisation deal to bring drug to US patients

London, UK, and Cambridge, MA, 19 December 2008 – Antisoma plc (LSE:ASM; USOTC: ATSMY) today announced that the United States Food and Drug Administration (FDA) has approved its tablet formulation of fludarabine phosphate ('oral fludarabine') as a second-line treatment for chronic lymphocytic leukaemia (CLL).

Oral fludarabine provides an alternative means to administer fludarabine that avoids the need for patients to have an intravenous infusion. Antisoma plans to make the drug available to US patients through a commercialisation deal. Talks are ongoing with a number of companies that have established oncology marketing operations in the US. Antisoma expects to conclude a deal early in 2009.

Glyn Edwards, Antisoma's CEO, said: "We are delighted that the FDA has cleared oral fludarabine for marketing in the US, giving Antisoma its first product approval. This puts us in a very good position to conclude a commercialisation deal for the drug. We anticipate a deal that allows us to realise the full value of oral fludarabine while placing the drug with a partner who can make it available as soon as possible as a new treatment option for US patients with CLL."

CLL is the most common leukaemia among adults in the western world. Fludarabine is an established drug in the treatment of CLL worldwide. Oral and intravenous formulations are in use in Europe, Canada and elsewhere, but until now only the intravenous formulation has been available in the US. In France and the UK, the oral formulation has been widely adopted, representing some 60 to 70% of fludarabine prescriptions.

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Details of the FDA approval of oral fludarabine

The FDA has approved fludarabine phosphate film-coated tablets as a single agent for the treatment of adult patients with B-cell chronic lymphocytic leukaemia (CLL) whose disease has not responded to or has progressed during or after treatment with at least one standard alkylating-agent containing regimen. The marketing authorisation has been granted under the FDA's accelerated approval provisions (21 CFR 314 subpart H ('accelerated approval')). Under these provisions, the sponsoring company is required to perform an additional clinical trial. The approved product label is available on the Antisoma website at www.antisoma.com and further details of the approval will be available in due course on the FDA website at www.fda.gov.

Details of Antisoma's commercial rights to oral fludarabine

Antisoma's rights to market fludarabine are specific to the oral (tablet) form of the drug and to the US market, where Antisoma has an exclusive licence from Bayer Schering Pharma AG. Oral fludarabine has US orphan drug status for treatment of CLL, providing seven years' exclusivity from approval. Antisoma has an

exclusive licence to US patents covering the oral formulation of fludarabine phosphate.

Oral fludarabine was added to the Antisoma pipeline through the acquisition of Xanthus Pharmaceuticals, Inc. in June 2008.

About CLL

CLL (chronic lymphocytic leukaemia) is a slowly progressing blood and bone marrow cancer, and is the most common type of leukaemia in adults in the United States. It is predominantly a disease of older people, with the majority of patients diagnosed being over 55. The American Cancer Society estimated that in 2007 there would be approximately 15,000 new cases of CLL in the United States and approximately 4,500 deaths from the disease.

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.

Disclaimer

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.