

# **NEWS RELEASE**

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# FDA approves Enzon IND for Santaris Pharma's Second New Cancer Drug

# Company receives \$5m milestone payment from Enzon Pharmaceuticals

Copenhagen, 26 January 2007

Santaris Pharma, the Danish biopharmaceutical company, announced today that it has received a milestone payment of US\$5 million from Enzon Pharmaceuticals Inc., its oncology partner, coinciding with the acceptance by the U.S. Food and Drug Administration (FDA) of the Investigational New Drug (IND) application for SPC/ENZ2968, an RNA antagonist of HIF-1 $\alpha$  (hypoxia-inducible factor 1alpha), being developed by Enzon for commercialisation outside Europe.

The IND is the result of the first six months of successful collaboration between Santaris Pharma and Enzon and was filed mid-December 2006 and subsequently approved by the FDA on 18th January, 2007. Enzon plans to initiate a phase I trial for the drug in the USA in the first half of 2007. Jeffrey Buchalter, Chairman and Chief Executive Officer of Enzon commented:

"This marks an important milestone for Enzon as we continue to focus our efforts on important oncology therapies. The continued advancement of the HIF-1alpha program demonstrates our commitment to developing a differentiated cancer portfolio."

Enzon entered into a partnership with Santaris Pharma in July 2006, as part of which it has licensed the non-European rights to the Santaris RNA antagonist of HIF-1 $\alpha$ , alongside a similar drug targeting another cancer gene called Survivin, The two companies are also collaborating on six additional proprietary RNA antagonists directed against recognised cancer gene targets selected by Enzon. The \$5m milestone payment by Enzon follows a previous \$3m milestone achieved in November 2006 which related to the final selection of molecular targets in the Enzon-Santaris drug discovery collaboration.



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Commenting on the FDA's IND approval, Dr Keith McCullagh, President and CEO of Santaris Pharma, said:

"This is the second RNA Antagonist based on Santaris Pharma's LNA chemistry to receive IND rapid review and acceptance by the FDA. We are delighted to be supporting Enzon's work on this and other development projects. Their experience and dedication to quality and efficiency in new oncology drug development has been exemplary."

HIF-1 $\alpha$  is an exciting new drug target in cancer and vascular biology. HIF-1 $\alpha$  is a key regulator of a large number of genes important in cancer biology, such as angiogenesis, cell proliferation, apoptosis and cell invasion. HIF-1 $\alpha$  is low in normal cells, but reaches high intracellular concentrations in a variety of cancers and is strongly correlated with poor prognosis and resistance to therapy. Drugs targeting HIF-1 $\alpha$  thus have the potential to target multiple cancer processes.

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#### **About Santaris Pharma**

Santaris Pharma is a clinical-stage biopharmaceutical company focused on developing a new class of RNAi drugs intended to switch off the expression of harmful genes. Called RNA Antagonists, these new drugs are being developed by Santaris and its corporate partners for the treatment of cancer and metabolic disorders. Created in May 2003 and backed by a broad group of leading international life science venture capital investors, Santaris Pharma completed a Euro



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40m second round of equity financing in May 2006. In July 2006, the Company entered into a global partnership with Enzon Pharmaceuticals of New Jersey to co-develop and commercialise a series of Santaris RNA Antagonists for improving the treatment of cancer.

Santaris Pharma's RNA Antagonist drug pipeline is based on its unique LNA technology. LNA drugs, with their high potency and biostability, have the potential to transform the field of RNAi medicines, making specific and effective gene silencing a reality in human medicine. If this potential is realised, even in part, it may be possible to design new drugs to treat the underlying genetic causes of disease rather than just the physical symptoms. Santaris Pharma holds the world wide patent rights to the exploitation of LNA in pharmaceuticals and presently has three drugs in preclinical or clinical development. The lead drug candidate, SPC2996, is currently undergoing international, multicenter, phase I/II clinical studies in Chronic Lymphocytic Leukemia (CLL).

For further company information see www.santaris.com

#### Forward Looking Statements

There are forward-looking statements contained herein, which can be identified by the use of forward-looking terminology such as the words "believes," "expects," "may," "will," "should", "potential," "anticipates," "plans" or "intends" and similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, events or developments to be materially different from the future results, events or developments indicated in such forward-looking statements. Such factors include, but are not limited to the timing, success and cost of clinical studies; the ability to obtain regulatory approval of products, market acceptance of, and continuing demand for Santaris or Enzon's products and the impact of competitive products and pricing. These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements. No assurance can be given that the future results covered by the forward-looking statements will be achieved. All information in this press release is as of the date of this press release and Santaris does not intend to update this information.