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FDA Grants Full Approval for DepoCyt(R) for the Treatment of Lymphomatous Meningitis

BRIDGEWATER, N.J., Apr 20, 2007 (BUSINESS WIRE) -- Enzon Pharmaceuticals, Inc. (Nasdaq: ENZN) today announced that the US Food and Drug Administration (FDA) has granted full approval for DepoCyt(R) (cytarabine liposome injection) for the treatment of patients with lymphomatous meningitis, a life-threatening complication of lymphoma. DepoCyt was originally approved under the Accelerated Approval regulations of Subpart H of the Food, Drug and Cosmetic Act, based on a preliminary demonstration of an increased complete response rate compared to unencapsulated cytarabine.

The full approval was based on findings from two randomized controlled clinical trials that included over 200 patients with neoplastic meningitis related to solid tumors, lymphoma or leukemia. The first study demonstrated that more patients with lymphomatous meningitis treated with DepoCyt showed an absence of neurological progression of the disease. The second study showed an increase in complete cytologic responses among patients treated with DepoCyt, as defined by a clearing of malignant cells in the cerebrospinal fluid (CSF).

"The FDA's full approval of DepoCyt is an important milestone for this unique product that has benefited those suffering from this devastating complication of cancer since its introduction to the market in 1999," said Jeffrey H. Buchalter, Chairman and Chief Executive Officer of Enzon. "Furthermore, we are pleased all of the FDA requirements have been met and we can continue to make this product available to the patients who need it."

DepoCyt is manufactured by SkyePharma Inc.

About DepoCyt

DepoCyt is a sustained release formulation of the chemotherapeutic agent, cytarabine, used for the treatment of patients with lymphomatous meningitis. Lymphomatous meningitis can be controlled with cytarabine, but because of the drug's short half-life, a spinal injection is required twice per week, whereas DepoCyt is dosed once every two weeks. DepoCyt gradually releases cytarabine into the cerebral spinal fluid resulting in a significantly extended half-life, prolonged exposure to the therapy, and a more uniform distribution.

Important safety information

DepoCyt(R) (cytarabine liposome injection) should be administered only under the supervision of a qualified physician experienced in the use of intrathecal cancer chemotherapeutic agents. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available. In all clinical studies, chemical arachnoiditis, a syndrome manifested primarily by nausea, vomiting, headache and fever, was a common adverse event. If left untreated, chemical arachnoiditis may be fatal. The incidence and severity of chemical arachnoiditis can be reduced by coadministration of dexamethasone. Patients receiving DepoCyt should be treated concurrently with dexamethasone to mitigate the symptoms of chemical arachnoiditis.

About Lymphomatous Meningitis

Lymphomatous meningitis is a complication of lymphoma that is characterized by the spread of the cancer to the central nervous system and the formation of secondary tumors within the thin membranes surrounding the brain. Symptoms can include numbness or weakness in the extremities, pain, sensory loss, double-vision or loss of vision, hearing problems, and headaches.

About Enzon

Enzon Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to the development, manufacturing, and commercialization of important medicines for patients with cancer and other life-threatening conditions. Enzon has a portfolio of four marketed products, Oncaspar(R), DepoCyt(R), Abelcet(R) and Adagen(R). The Company's drug development programs utilize several cutting-edge approaches, including its industry-leading PEGylation technology platform used to create product candidates with benefits such as reduced dosing frequency and less toxicity. Enzon's PEGylation technology was used to develop two of its products, Oncaspar and Adagen, and has created a royalty revenue stream from licensing partnerships for other products developed using the technology. Enzon also engages in contract manufacturing for several pharmaceutical companies to broaden the Company's revenue base. Further information about Enzon and this press release can be found on the Company's web site at www.enzon.com.

About SkyePharma Inc.

SkyePharma Inc. is a wholly owned subsidiary of Blue Acquisition Corp., a Delaware corporation, which is controlled and funded by a group of financial investors including MPM Capital, OrbiMed Advisors, HBM Bioventures (Cayman) LTD. and Sanderling Ventures,. This business is based in San Diego, CA, and formulates, develops and manufactures controlled-release injectable products based on two proprietary drug delivery platforms: DepoFoam and Biospheres. Revenues are generated from two marketed products: DepoCyt for lymphomatous meningitis and DepoDur for the treatment of post-surgical pain.

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, Enzon's products and the impact of competitive products and pricing. A more detailed discussion of these and other factors that could affect results is contained in our filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the 12-month period ended December 31, 2006. 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 Enzon does not intend to update this information.

SOURCE: Enzon Pharmaceuticals, Inc.

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