Enzon Announces Publication of Preclinical Study Data of PEG-SN38 in Pediatric Neuroblastoma

Results indicate PEG-SN38 produced superior antitumor activity compared to irinotecan

BRIDGEWATER, N.J., Oct 05, 2010 (BUSINESS WIRE) -- Enzon Pharmaceuticals, Inc. (Nasdaq: ENZN) today announced the publication of preclinical data demonstrating that PEG-SN38 (EZN-2208), the Company's novel PEGylated DNA topoisomerase I inhibitor, led to significantly greater tumor regression as compared to CPT-11 (irinotecan) in both *in vitro* and *in vivo* models of pediatric neuroblastoma. The data were published in the October 1, 2010 issue of *Clinical Cancer Research* (Pastorino, F. et al, volume 16, number 9, pp. 4809-4821).

"PEG-SN38 demonstrated complete and durable tumor regression in a series of experimental models that were designed to reflect the clinical progression of neuroblastoma in pediatric patients," said Ivan Horak, M.D., Enzon's President of Research and Development and Chief Scientific Officer, and one of the study's authors. "Neuroblastoma is the second-most common pediatric solid tumor, with a five year-survival rate of only 25 percent. The limited efficacy and significant toxicities associated with currently available treatment options underscore the need for new and better therapies. The present findings form the basis for our ongoing Phase I study of PEG-SN38 in pediatric patients with solid tumors which may include patients with neuroblastoma."

The preclinical study was designed to assess the antitumor activity of PEG-SN38 relative to CPT-11, a chemotherapeutic drug that is currently used in the clinical treatment of neuroblastoma and other solid tumors. CPT-11 has shown activity against neuroblastoma that has become resistant to standard treatments, and its non-hematological toxicities are considered transient and manageable. However, its limitations include the inconvenience of current daily schedule and gastrointestinal side effects. While direct administration of SN38 may overcome these limitations, its low solubility does not allow formulation in conventional pharmaceutical vehicles that would permit administration to patients. Enzon's proprietary customized linker-enhanced PEGylation technology allows a soluble, more potent, and longer-lasting version of the drug, which may be administered weekly or once every three weeks.

The preclinical study employed *in vitro* models to assess the cytotoxicity of PEG-SN38, while *in vivo* therapeutic efficacy was evaluated in terms of survival, antitumor and antiangiogenic activity in three different animal models. The animal models were designed to closely reflect the primary, metastatic, and advanced stages of neuroblastoma in pediatric patients.

The data show that PEG-SN38 was 100-fold more potent than CPT-11 *in vitro*, as measured by the induction of cancer-cell death as well as through anti-angiogenesis and drug resistance indicators. *In vivo*, treatment with PEG-SN38 resulted in no detectable tumor at the end of the studies, whereas only minor therapeutic effect was observed with CPT-11. PEG-SN38 also blocked tumor relapse following treatment with other drugs commonly used to treat neuroblastoma. In tumors that were resistant to these drugs, use of PEG-SN38 resulted in 100 percent curability. These data further substantiate the superior preclinical profile of PEG-SN38 compared with CPT-11 that has been previously observed in models of human tumors (see Sapra et al. 2008. *Clin Cancer Res* 14: 1888-1896 and Sapra et al., 2009. *Hematologica* 94: 1456-1459).

A copy of the publication is available through the website of the American Association of Cancer Research website at http://clincancerres.aacrjournals.org.

About PEG-SN38 (EZN-2208)

SN38 is the active metabolite of the widely used cancer drug irinotecan, marketed as Camptosar(R) in the U.S. Although unmodified SN38 is 1,000 times more potent than CPT-11, it has not been converted into a viable drug candidate because of its insolubility. Using Enzon's proprietary customized linker-enhanced PEGylation technology, the Company developed PEG-SN38 (EZN-2208), which results in a compound with excellent pharmaceutical properties as shown in animal models: increased solubility, higher exposure, and longer half-life than unmodified SN38. PEG-SN38 is currently being evaluated in ongoing Phase II clinical trials in metastatic breast cancer and metastatic colorectal carcinoma, and in a Phase I study in pediatric patients with solid tumors and lymphomas.

About Pediatric Neuroblastoma

Neuroblastoma is a cancer that arises in immature nerve cells and affects mostly infants and children (National Cancer Institute). It is by far the most common cancer in infants and accounts for seven percent of all cancers in children. There are approximately 650 new cases of neuroblastoma each year in the United States, and 90 percent of cases are diagnosed before

age 5. In about two out of three cases, the cancer is already metastatic at the time of diagnosis (American Cancer Society). Treatment is currently successful in less than half of patients who present with metastatic disease. Five-year survival of neuroblastoma is approximately 25 percent.

About Enzon

Enzon Pharmaceuticals, Inc. is a biopharmaceutical company dedicated to the development of innovative medicines for patients with cancer. Enzon's drug development programs utilize several approaches, including its cutting-edge proprietary customized linker-enhanced PEGylation technology and mRNA antagonists using the Locked Nucleic Acid (LNA) technology. Enzon receives a royalty revenue stream from licensing partnerships for other products developed using the proprietary PEGylation technology. Further information about Enzon and this press release can be found on the Company's web site at www.enzon.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 for Enzon's product candidates; the ability to obtain regulatory approval of product candidates, Enzon's ability to obtain the funding necessary to develop its product candidates, market acceptance of, and demand for, Enzon's product candidates and the impact of competitive products, pricing and technology. 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 year ended December 31, 2009. 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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