Enzon Presents Data From Phase II PEG-SN38 (EZN-2208) Study in Patients With Metastatic Breast Cancer

PISCATAWAY, NJ -- (MARKET WIRE) -- 12/08/11 -- Enzon Pharmaceuticals, Inc. (NASDAQ: ENZN) today presented data from a Phase II, open-label study in which PEG-SN38 (EZN-2208) demonstrated notable activity in patients with previously treated metastatic breast cancer. The data were presented in a poster session (Poster P3-16-18) at the San Antonio Breast Cancer Symposium in San Antonio, TX.

"Despite the numerous treatments available, effective therapies for patients with previously treated metastatic breast cancer are needed," said Joyce A. O'Shaughnessy, MD, a breast cancer specialist at Texas Oncology, Baylor Sammons Cancer Center, and US Oncology, and the principal investigator of the study. "In this trial, PEG-SN38 resulted in a significant overall response rate in previously treated patients, as well as a significant proportion of patients remaining progression-free at 6 months. PEG-SN38 further demonstrated similar activity in both hormone- and non-hormone-expressing tumors, suggesting it may be effective in 'triple-negative' forms of breast cancer."

The study was designed to evaluate the efficacy of single-agent PEG-SN38 in 164 female patients who had previously been treated for metastatic breast cancer with either anthracycline and taxane (AT, up to 2 prior lines of therapy) (n=81), or anthracycline, taxane and capecitabine (ATX, up to 4 prior lines of therapy) (n=83). The primary objective of the study was to determine overall response and secondary objectives including duration of response, progression-free survival (PFS), overall survival (OS) and safety.

Overall response was found to be meaningful in both the AT group (21%) and the ATX group (11%), with both groups also demonstrating clinical benefit rates (e.g. percentage of patients with objective tumor responses plus those with stable disease as their best response). For the AT and ATX cohorts, respectively, the median duration of response was 4.2 and 5.2 months; median PFS values were 3.8 and 3.4 months, respectively; and median OS values were 10.5 and 8 months, respectively. PEG-SN38 was generally safe and well tolerated in these heavily pretreated patients, with neutropenia, diarrhea and leukopenia being the most common adverse events.

Aby Buchbinder, MD, Enzon's Vice President of Clinical Development, commented, "These data corroborate earlier findings demonstrating PEG-SN38's robust anti-tumor activity in breast cancer, including triple-negative models. Furthermore, they contribute to the substantial clinical evidence indicating the potential of PEG-SN38 to deliver meaningful therapeutic benefit in multiple oncology indications in which the full benefit of irinotecan cannot be realized due to toxicity."

Investigators concluded that PEG-SN38 warrants further clinical study in metastatic breast cancer. Enzon is currently seeking a strategic partner to further develop and commercialize PEG-SN38, in this indication as well as in other malignancies, including pediatric neuroblastoma, in which the product candidate has demonstrated notable anti-tumor activity in a Phase 1 study of PEG-SN-38 in children with refractory solid malignancies. Absent such a partnership, the Company does not intend to fund further development of PEG-SN38.

About PEG-SN38 (EZN-2208)

Through the use of our PEGylation technology, we designed PEG-SN38 (EZN-2208), a PEGylated conjugate of SN38, to offer therapeutic advantages over unmodified SN38 and existing therapies. The PEGylated version allows parenteral delivery, increased solubility, higher exposure, more profound deoxyribonucleic acid (DNA) damage, inhibition of angiogenesis, and longer apparent half-life of SN38 as compared to irinotecan.

About Enzon

Enzon Pharmaceuticals, Inc. is a biotechnology company dedicated to the research and development of innovative therapeutics for cancer patients with high unmet medical needs. Enzon's drug-development programs utilize two platforms -- Customized PEGylation Linker Technology (Customized Linker Technology®) and third-generation mRNA-targeting agents utilizing the Locked Nucleic Acid (LNA) technology. Enzon currently has four compounds in human clinical development and multiple novel LNA targets in preclinical research. Enzon receives royalty revenues from licensing arrangements with other companies related to sales of products developed using its proprietary Customized Linker Technology. Further information about Enzon and this press release can be found on the Company's website 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 Enzon's product candidates, Enzon's ability to obtain a strategic partner to develop and commercialize PEG-SN 38, 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 Enzon's filings with the U.S. Securities and Exchange Commission, including Enzon's most recent Annual Report on Form 10-K for the year ended December 31, 2010. 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.

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