

Enzon to Begin Phase 1 Study of Novel Androgen Receptor mRNA Antagonist in Castration-Resistant Prostate Cancer

BRIDGEWATER, N.J.--(BUSINESS WIRE)-- Enzon Pharmaceuticals, Inc. (Nasdaq: ENZN) today announced the Investigational New Drug (IND) approval by the US Food and Drug Administration (FDA) and plan to commence enrollment into a Phase 1a/1b study shortly. The study will evaluate the safety and tolerability of EZN-4176, the company's novel androgen receptor (AR) mRNA antagonist, for the treatment of patients with castration-resistant prostate cancer (CRPC). Unlike other novel agents for CRPC that inhibits androgen production or receptor activation, EZN-4176 is unique in its ability to eliminate androgen receptor.

The open-label, Phase 1a/1b, non-randomized study will enroll adult patients with CRPC, who will receive EZN-4176 as a weekly, one-hour intravenous infusion in four-week treatment cycles. The study will have two phases: Phase 1a will determine the maximum tolerated dose, after which pharmacokinetic and pharmacodynamic studies will be conducted at one or more dose levels in Phase 1b to determine the recommended Phase 2 dose.

Enzon's initiation of this study follows the presentation of preclinical data at the 2010 EORTC-NCI-AACR meeting demonstrating potent anti-tumor activity for EZN-4176, both alone and in combination with MDV-3100, a novel AR antagonist that is currently in Phase 3 testing.

Prostate cancer is a common cause of cancer-related deaths among men in the United States, a fact that underscores the need for new treatment options, particularly for late-stage disease. In the preclinical setting, EZN-4176 exhibited robust tumor-growth inhibition that correlated with down-modulation of the AR, and consequently inhibition of transcription activity.

Ivan Horak, MD, Enzon's president of research and development and chief scientific officer, commented, "The initiation of this study marks an important step in the advancement of Enzon's third-generation mRNA antagonists, which are based on proprietary Locked Nucleic Acid technology. We believe that the enhanced stability, potency and affinity of these compounds will translate to meaningful improvements in the treatment of CRPC and other cancers with high unmet medical need."

About EZN-4176 (androgen receptor mRNA antagonist)

EZN-4176, an androgen receptor (AR) mRNA antagonist, is a Locked Nucleic Acid (LNA) oligonucleotide that specifically down-modulates AR mRNA. In vitro, EZN-4176 has been shown to down-modulate AR mRNA and protein, and inhibit AR transcriptional activity and cell growth. AR is widely recognized as an important therapeutic target for the treatment of prostate cancer, as androgens are essential to prostate tumor growth and viability. EZN-4176 is based on Enzon's proprietary LNA technology platform targets, which were licensed from Santaris Pharma A/S. The LNA technology allows the antisense molecule to have high-potency resistance to nuclease destruction, and administration of the molecule intraveneously when prepared in saline (without any delivery vehicle).

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 Technology utilizing PEGylation and mRNA antagonists using the Locked Nucleic Acid (LNA) technology. Enzon receives a royalty revenue stream from licensing arrangements for other products developed using the proprietary Customized Linker 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.

Argot Partners
Andrea Rabney, 212-600-1902
andrea@argotpartners.com

Source: Enzon Pharmaceuticals, Inc.

News Provided by Acquire Media