



**Pharmacodynamic Data from Syndax Pharmaceutical's ENCORE 301 Study in Advanced Breast Cancer to be Highlighted at the AACR Molecular Targets and Cancer Therapeutics Conference 2011**

**-- Oral presentation and Press Conference will take place Sunday, November 13, 2011 --**

Waltham, Mass. – November 2, 2011 – [Syndax Pharmaceuticals, Inc.](http://www.syndaxpharma.com), a clinical-stage epigenetics oncology company, announced today that pharmacodynamic analysis in a subset of patients from ENCORE 301, a randomized phase 2 study of exemestane with and without entinostat in advanced breast cancer patients, will be presented in an oral session at the [American Association for Cancer Research \(AACR\) Molecular Targets and Cancer Therapeutics Conference](http://www.aacr.org).

The positive data was from [ENCORE 301](http://www.encyclo.com) (ENTinostat Combinations Overcoming RESistance), a multicenter, randomized, double-blind, placebo-controlled, phase 2 study of exemestane with and without entinostat in 130 postmenopausal women with locally recurrent or metastatic estrogen receptor-positive breast cancer, progressing on treatment with the non-steroidal aromatase inhibitors anastrozole or letrozole. The study which met the primary endpoint of progression free survival (PFS) was presented at the ASCO Breast Cancer Symposium in September earlier this year.

The pharmacodynamic data will be presented by Peter Ordentlich, Ph.D. in an oral session called the Proffered Paper Session 1 on Sunday, November 13, 2011 from 4:30 to 6:00 PM PT.

**For media**

The data will be discussed during a press conference on Sunday, November 13, 2011 at 7:30 AM PT in room 2004 of the Moscone Convention Center. To dial in to the webcast please dial Toll-Free (US & Canada) (888) 647-7462 or International Dial-In (Toll): (201) 604-0169.

**Breast Cancer and Hormone Therapy**

Annually about 207,000 women have breast cancer in the United States and about 20,000 of them have metastatic breast cancer (MBC). Approximately 70 percent of women with breast cancer have ER+ breast cancer. Blocking estrogen activity with aromatase inhibitors represents an effective treatment for most ER+ MBC patients, however acquired drug resistance to aromatase inhibitors leads to disease progression requiring less effective, more toxic chemotherapies.<sup>1</sup> Delaying resistance and disease progression represents a significant unmet need that could prolong survival while decreasing health care costs associated with chemotherapy and hospitalization.

**About Entinostat**

Syndax's lead product entinostat is a novel, oral small molecule inhibitor of class I histone deacetylases, key enzymes that alter the structure of chromatin to control gene expression. Entinostat is differentiated from other members of the class through its unique selectivity profile, pharmacokinetic properties and safety profile. Entinostat has been studied in more than 600 cancer patients where objective tumor responses have been observed in both solid and hematologic malignancies. Breast cancer animal models demonstrated that resistance to aromatase inhibitors occurs through up-regulation of growth factor signaling pathways and down-regulation of estrogen receptor-alpha (ER). Entinostat effectively down-regulates growth factor signaling in breast cancer cells where these pathways are active. Entinostat also up-regulates the expression of ER in breast cancer cells which have negligible or undetectable levels of ER. The ability to target multiple mechanisms of resistance establishes entinostat as a promising candidate for preventing and overcoming aromatase inhibitor

resistance through epigenetic modulation. In pre-clinical testing entinostat induced tumor regression when combined with an aromatase inhibitor after the development of hormone resistance.

Additional [phase 2 studies](#) with entinostat have demonstrated promising results in combination with the EGFR-TKI erlotinb (ENCORE 401) in non-small cell lung cancer and as a single agent in Hodgkin's lymphoma (ENGAGE 501). Results from the ENCORE clinical program have provided the basis for moving entinostat in pivotal, phase 3 testing across a platform of breast and lung cancer indications.

### **About Syndax**

Syndax Pharmaceuticals, Inc. is a Waltham, MA-based, late-stage, oncology-focused pharmaceutical company. The company is building a portfolio of new oncology products to extend and improve the lives of patients by developing and commercializing novel cancer therapies in optimized, mechanistically driven combination regimens. Syndax has worldwide rights to develop and commercialize entinostat which has shown [promise](#) in randomized clinical trials in solid tumors. Syndax is backed by top-tier Venture Capital firms: Domain Associates, MPM Capital, Avalon, Pappas and Forward Ventures. Formed in 2005, Syndax's intellectual property is based on work from scientific founder Ronald Evans, Ph.D., recipient of the 2004 Albert Lasker Prize for Basic Medical Research, a Member of the National Academy of Sciences, a professor at the Salk Institute for Biological Studies and a Howard Hughes Medical Institute Investigator. For more information please visit [www.syndax.com](http://www.syndax.com).

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1. Hurvitz, S, Pietras, R. Rational Management of Endocrine Resistance in Breast Cancer, *Cancer*, 2385- 2397 (2008).

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