Results of Syndax Pharmaceutical’s ENCORE 301 Study in Advanced Breast Cancer to be Highlighted at the ASCO Breast Cancer Symposium 2011

-- Oral presentation will take place Saturday, September 10, 2011 --

Waltham, Mass. – August 24, 2011 – Syndax Pharmaceuticals, Inc., a clinical-stage epigenetics oncology company, announced today that safety and efficacy data from ENCORE 301 will be presented in an oral session at the ASCO Breast Cancer Symposium 2011 on Saturday, September 10 in San Francisco, CA.

“Endocrine therapy, such as aromatase inhibitors, is the backbone of treatment of estrogen receptor positive (ER+) breast cancer but unfortunately resistance in women with advanced breast cancer almost always develops necessitating a switch to less targeted and more toxic options such as chemotherapy,” said Joanna Horobin, MD, president and chief executive officer of Syndax. “Our ENCORE 301 study was designed to demonstrate whether combining entinostat with an aromatase inhibitor can serve as a bridge to extend the benefit of hormone therapy while delaying the move to chemotherapy.”

ENCORE 301 (ENTinostat Combinations Overcoming REsistance) is 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 primary endpoint of the study is progression free survival (PFS). Other endpoints include objective response rate (ORR), clinical benefit rate (CBR), overall survival (OS) and safety and tolerability.

The data will be presented in an oral session on Saturday, September 10, 2011 from 10:00 to 11:30 AM PT. Below you can find details regarding the presentation:

**Session:** General Session VIII: Advances in Hormone Receptor-positive Breast Cancer and Host Factors

**Chair:** Joyce O’Shaughnessy, MD, Baylor Sammons Cancer Center, Texas Oncology, US Oncology Research Inc.

**Abstract #:** 268

**Title:** Results of ENCORE 301, a randomized, phase II, double-blind, placebo-controlled study of exemestane with or without entinostat in postmenopausal women with locally recurrent or metastatic estrogen receptor-positive (ER+) breast cancer progressing on a nonsteroidal aromatase inhibitor (AI).

**Presenter:** Denise Yardley, MD, Sarah Cannon Research Institute

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. 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 erlotinib (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, oncology-focused pharmaceutical company. Syndax 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. Formed in 2005, the company'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. Syndax has worldwide rights to develop and commercialize entinostat and is backed by top-tier Venture Capital firms: Domain Associates, MPM Capital, Avalon, Pappas and Forward Ventures. For more information please visit www.syndax.com.

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