Survival Benefit With Syndax Pharmaceuticals' Entinostat Maintained in Women with Advanced Breast Cancer

--Seven-month survival advantage for exemestane plus entinostat treated patients--

--Data presented at San Antonio Breast Cancer Symposium--

Waltham, Mass. – December 7, 2011 – Syndax Pharmaceuticals, Inc. announced today that, with a 23-month patient follow up of ENCORE 301, a multicenter, randomized, double-blind, placebo-controlled, phase 2 study of exemestane with and without entinostat in 130 patients with locally recurrent or metastatic estrogen receptor-positive breast cancer, the median overall survival of exemestane plus entinostat patients reached 26.9 months versus 19.8 months for exemestane plus placebo. This represents a 42% reduction (p=0.04) in the risk of dying for these patients. Previously presented data from ENCORE 301 demonstrated a near doubling in the progression-free survival (PFS) (4.3 vs. 2.3 months) with exemestane plus entinostat and the identification of a subset of these patients whose median PFS reached 8.5 months. The updated data is being presented today, December 7, 2011, at the **San Antonio Breast Cancer Symposium** in San Antonio, Texas.

"It is both exciting and encouraging to see after two years of follow up that patients treated with entinostat and exemestane benefited from an additional seven months of overall survival," said Denise A. Yardley, MD, breast program leader, senior investigator at the Sarah Cannon Research Institute and principal investigator of the study. "This encouraging signal of not only a progression-free survival advantage (4.3 months vs 2.3 months) but also of an overall survival benefit for this combination, coupled with an excellent safety and tolerability profile, provide the platform for the larger scale confirmatory, randomized, phase 3 study anticipated to begin enrollment in the first half of 2012."

Highlights of the data to be presented include:

- Overall survival: 26.9 months for exemestane + entinostat vs. 19.8 months for exemestane + placebo HR = 0.58 (95%CI: 0.34, 0.97) p = 0.04

- Progression-free survival: 4.3 months for exemestane + entinostat vs. 2.3 months for exemestane + placebo HR = 0.73 (95%CI: 0.49, 1.09) p = 0.06; 1-sided significance prospectively defined as <0.10

- Progression-free survival of 8.5 months for exemestane + entinostat in subset of patients with increased protein acetylaton vs. 2.8 months in non acetylators HR = 0.32 (95%CI: 0.13, 0.79)

- Trend in improved progression-free survival in hormone-resistant vs. hormone-sensitive patients

- Exemestane combined with entinostat was well tolerated with the most frequent adverse events consisting of fatigue, gastrointestinal disturbances and hematologic abnormalities

"The continued survival benefit increases our confidence that entinostat will play a critical role in the treatment of women with estrogen receptor-positive metastatic breast cancer," said Joanna Horobin, MD, president and chief executive officer of Syndax. "We look forward to moving entinostat into phase 3 clinical testing in 2012."

San Antonio Breast Cancer Symposium
Presentation Date/Time: Wednesday, December 7 from 5:00 PM - 7:00 PM
Poster Title: Entinostat, a Novel Histone Deacetylase Inhibitor, Added to Exemestane Improves PFS in Advanced Breast Cancer in a Randomized, Phase II, Double-Blind Study
Session: POSTER DISCUSSION I: Endocrine Resistance
Abstract Number: PD01-04
Location: Ballroom A

Breast Cancer and Hormone Therapy
Approximately 230,000 new cases of invasive breast cancer are diagnosed in women annually in the United States and there are approximately 150,000 women living with metastatic breast cancer (MBC). Over 70 percent of women with breast cancer have estrogen receptor-positive (ER+) breast cancer. The most effective cancer treatments target the underlying biology and in breast cancer the most common oncogenic driver is estrogen receptor signaling. 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, ultimately requiring less effective, more toxic chemotherapies.[1] 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 (ERα). 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.

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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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