Entinostat Demonstrates Activity in Hodgkin's Lymphoma

--Data presented at American Society of Hematology Annual Meeting and Exposition--

Waltham, Mass. – December 11, 2011 – Syndax Pharmaceuticals, Inc. announced today that data from ENGAGE 501, a multicenter, phase 2 study, demonstrated entinostat, a novel, oral small molecule inhibitor of class I histone deacetylases, showed activity as a single agent in patients with relapsed or refractory Hodgkin's lymphoma (HL). This data is being presented today, December 11, from 6:00 to 8:00 PM PT at the American Society of Hematology Annual Meeting and Exposition in San Diego.

"Showing activity in this hard-to-treat patient population, demonstrates potential for entinostat to treat Hodgkin's lymphoma," said Anas Younes, MD, professor, department of lymphoma/myeloma, division of cancer medicine, The University of Texas MD Anderson Cancer Center. "These results are consistent with what has been seen with other HDAC inhibitors with a lower rate of toxicity warranting further study of entinostat particularly in combination strategies and at an earlier stage of disease."

Highlights of the data include:

- Antitumor activity observed in HL patients progressing after SCT with bulky disease in about a third of patients within two cycles of therapy
- Progression-free survival (PFS) showed durable responses in bulky disease patients
- Overall survival (OS) was an exploratory endpoint with data that is still maturing
- Entinostat was well tolerated and the safety profile is consistent with previous studies allowing for future combination treatments.

"We are pleased to see that the results of ENGAGE 501 provide evidence of single-agent activity for entinostat in Hodgkin's lymphoma," said Joanna Horobin, MD, president and chief executive officer of Syndax. "Given this data combined with the recently reported ENCORE 301 breast cancer and the ENCORE 401 NSCLC data, we are enthusiastic about the potential to improve outcomes in both solid tumors and hematological malignancies."

American Society of Hematology Annual Meeting and Exposition
Details on the ENGAGE 501 presentation and additional data presentations are below:

Presentation Date/Time: Sunday, December 11 from 6:00 PM - 8:00 PM
Poster Title: The HDAC Inhibitor Entinostat (SNDX-275) Induces Clinical Responses in Patients with Relapsed and Refractory Hodgkin's Lymphoma: Results of ENGAGE-501 Multicenter Phase 2 Study
Program/Session: Oral and Poster Abstracts, 624. Lymphoma- Therapy with Biologic Agents, excluding Pre-Clinical Models: Poster II
Abstract Number: 2715
Location: Hall GH (San Diego Convention Center)

Presentation Date/Time: Saturday, December 10, 2011: 5:30 PM-7:30 PM
Poster Title: HDAC and LSD1 Inhibitors Synergize to Induce Cell Death in Acute Leukemia Cells
Program/Session: Oral and Poster Abstracts, 604. Molecular Pharmacology, Drug Resistance: Poster I
Abstract Number: 1427
Location: Hall GH (San Diego Convention Center)

Presentation Date/Time: Monday, December 12 from 6:00 PM - 8:00 PM

Poster Title: Entinostat, a Novel Histone Deacetylase (HiDAC) Inhibitor Enhances the Anti-Tumor Activity of Bortezomib (BTZ) in Rituximab-Chemotherapy Sensitive and Resistant Lymphoma Cell Lines
Program/Session: Oral and Poster Abstracts, 625. Lymphoma - Pre-Clinical - Chemotherapy and Biologic Agents: Poster III
Abstract Number: 3734
Location: Hall GH (San Diego Convention Center)

Hodgkin's Lymphoma
Hodgkin's lymphoma (HL) is a cancer of lymph tissue found in the lymph nodes, spleen, liver, bone marrow, and other sites. It is most common among people ages 15 - 35 and 50 - 70. Although the cause is not known, past infection with the Epstein-Barr virus (EBV) is thought to contribute to some cases and patients with HIV infection are more at risk than the general population. It is estimated that 8,830 people in the US will be diagnosed with and 1,300 will die of the disease in 2011, with the prognosis of patients with relapsed HL being particularly poor. HDACi have shown promise in treating this disease. Preclinical studies have identified at least three complementary mechanisms to explain how HDACi may be effective in the treatment of HL (Buglio, Blood 2008): induction of apoptosis, regulation of cytokines and chemokines and alterations of cancer/testis antigens (Jóna et al., Exp Hematol. 2011).

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. Randomized, placebo-controlled phase 2 studies with entinostat have demonstrated promising results in combination with aromatase inhibitors in breast cancer (ENCORE 301) and with the EGFR-TKI erlotinb (ENCORE 401) in non-small cell lung cancer. 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 and in phase 2 clinical trials in Hodgkin's lymphoma. 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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