Syndax Pharmaceuticals Inc. to Present Entinostat Data Showing Benefit in Combination in Advanced Breast Cancer at ASCO

WALTHAM, Mass., May 24 /PRNewswire/ -- Syndax Pharmaceuticals, Inc., a clinical-stage epigenetics company, announced today that abstracts related to its lead anti-cancer compound, entinostat, an orally bioavailable, selective, class I histone deacetylase (HDAC) inhibitor, will be presented at the 46th American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

"The data and information we are presenting at the Annual ASCO Meeting support entinostat's promise in combination with targeted therapies," said Joanna Horobin, president and chief executive officer. "Entinostat's potential to reprogram tumors and restore their sensitivity to targeted therapies may help address the need to better treat patients who often cycle through multiple treatments that become increasingly ineffective over time."

Syndax will present safety and efficacy analyses from the Company's Phase 2 trial of entinostat in combination with aromatase inhibitors (AI) in the treatment of 27 postmenopausal women with estrogen receptor (ER) positive breast cancer. In addition, two posters will be presented during the ASCO's new "Trials in Progress" session, which is designed to facilitate awareness of the scientific rationale and dialogue about active, clinical trials.

Information regarding the ASCO presentations is below and full abstracts are now available on the ASCO website at http://meetingplanner.asco.org.

**Presentation Date/Time:** Saturday, June 5 from 2:00 PM - 6:00 PM

**Poster Title:** Phase II data for entinostat, a class 1 selective histone deacetylase inhibitor, in patients whose breast cancer is progressing on aromatase inhibitor therapy

**Abstract Number:** #1052 (Poster Board 23E)

**Location:** S Hall A2

**Presentation Date/Time:** Monday, June 7 from 8:00 AM - 12:00 PM

**Poster Title:** A double-blind, randomized, placebo-controlled Phase II study of the steroidal aromatase inhibitor exemestane with and without the isoform selective histone deacetylase inhibitor (HDACi) entinostat in metastatic breast cancer (MBC)

**Abstract Number:** #TPS128 (Trials in Progress Poster Session)

**Location:** S Hall A2

**Presentation Date/Time:** Monday, June 7 from 8:00 AM - 12:00 PM

**Poster Title:** ENGAGE-501: Phase II study investigating the role of epigenetic therapy with entinostat (SNDX-275) in relapsed and refractory Hodgkin's lymphoma (HL)

**Abstract Number:** #TPS298 (Trials in Progress Poster Session)

**Location:** S Hall A2
About HDAC Inhibitors
Research has shown that HDACs are involved in the expression of various genes that regulate cell growth, differentiation and apoptosis. Such genes are frequently silenced in cancer cells through the over-expression of enzymes including HDACs. HDACs are therefore recognized as promising targets for cancer treatment. Further, studies have demonstrated that HDAC inhibition can significantly enhance anti-cancer activity when used in combination with a broad range of anti-cancer agents. The potential therefore exists to restore the sensitivity of tumor cells that have previously been rendered resistant to targeted therapy.

About Entinostat
Entinostat is an orally bioavailable, selective, class I histone deacetylase (HDAC) inhibitor. Entinostat is currently being investigated in randomized, Phase 2 clinical studies in combination with the aromatase inhibitor, exemestane, for the treatment of metastatic or locally advanced ER+ breast cancer; in combination with erlotinib in advanced non-small-cell lung cancer, and in combination with azacitidine in myelodysplastic syndrome. Phase 2 single arm studies in non-small cell lung cancer and colorectal cancer, also are being conducted in combination with azacitidine; and a Phase 2 in Hodgkin's lymphoma is ongoing with single agent entinostat. Entinostat's long half-life allows for weekly or every-other-week oral dosing.

Limitations of Targeted Therapies
Many patients receive sequential anti-cancer therapies; switching from one therapy to another each time the patient no longer benefits from a given therapy. Over time, each subsequent therapy has a lower likelihood of working. For example, patients with ER+ metastatic breast cancer frequently receive several sequential hormonal therapies. While the likelihood of benefit from each subsequent hormonal treatment decreases, for many ER+ patients hormonal agents, including aromatase inhibitors, represent the preferred treatment over chemotherapy because of their favorable risk benefit profile. Over time, breast tumors may lose expression and/or function of the estrogen receptor through epigenetic mechanisms resulting in resistance to hormonal therapies. Preliminary data support the concept that HDAC inhibitors may be able to "reprogram" tumors resulting in the ability to overcome resistance to targeted agents, including hormonal agents.

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, PhD, 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 holds rights to entinostat from Bayer Schering Pharma and is backed by top-tier Venture Capital firms: Domain Associates, MPM Capital, Avalon, Pappas and Forward Ventures.

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