



Syndax Pharmaceuticals' Entinostat Shows Clinical Promise in Patients with Advanced Hormone Refractory Breast Cancer

- Data to be presented at the American Society of Clinical Oncology annual meeting –

Waltham, Mass. – June 4, 2010 – Syndax Pharmaceuticals, Inc., a clinical-stage epigenetics oncology company, reported final results from the Phase 2, open-label ENCORE 303 trial in post-menopausal women with advanced, estrogen receptor (ER) positive breast cancer who were progressing on aromatase inhibitor (AI) therapy. Safety and efficacy results from the trial will be presented in a poster at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, IL tomorrow, Saturday, June 5, 2010.

“These findings are significant given that the patients enrolled were heavily hormonally pre-treated and relatively hormone resistant,” said Joanna Horobin, president and chief executive officer of Syndax. “Resistance to AI therapy is multi-factorial and involves up-regulation of growth factor signaling pathways and down-regulation of estrogen receptor expression which may result from epigenetic modifications to the DNA and associated proteins. The disease stabilization achieved with the addition of entinostat supports our hypothesis that entinostat has the ability to normalize gene expression, thereby restoring sensitivity to targeted agents. We are optimistic that our ongoing ENCORE 301 study - a double-blind, randomized, placebo-controlled phase 2 study of entinostat in combination with the aromatase inhibitor exemestane, will provide further evidence supporting the clinical benefit and tolerability of entinostat in combination with aromatase inhibitors.”

The primary endpoint of the study was Clinical Benefit Rate (CBR), defined as the proportion of patients who experience a complete or partial response or stable disease during the first six cycles of study treatment. Of the 26 evaluable patients in the ENCORE 303 study, one achieved a partial response (PR) and three achieved SD of greater than six months. The CBR of 15.4% exceeded the pre-specified rate of 5% defined in the study design with a p-value of 0.039. An additional six patients experienced SD between four and six months. Secondary endpoints were objective response (OR) and progression-free survival (PFS), which were 3.9% and a median of 4.8 months, respectively. Overall survival, pharmacokinetics, and correlation of selected biomarkers with clinical outcome were also measured. The most common adverse events considered to be related to entinostat were fatigue, nausea and diarrhea. No unexpected side effects were observed.

Syndax is also presenting two posters during the Society's new “Trials in Progress” session. These include abstract TPS128, which reviews ENCORE 301, a double-blind, randomized, placebo-controlled phase 2 study of entinostat in combination with exemestane, an aromatase inhibitor, in 114 post-menopausal women with ER positive metastatic breast cancer; and abstract TPS298, which reviews ENGAGE 501, an open-label, multicenter Phase 2 study in patients with Hodgkin's lymphoma. Data are anticipated from ENCORE 301 and ENGAGE 501 within 12 months.

Information regarding the ASCO presentations and full abstracts may be found on the ASCO website at <http://meetingplanner.asco.org>.



About Entinostat

Entinostat is an orally bioavailable, highly selective, class I histone deacetylase (HDAC) inhibitor with a long half-life that may allow for weekly or every-other-week dosing. Entinostat is currently being investigated in several randomized, phase 2 clinical studies including advanced ER+ breast cancer in combination with aromatase inhibitors and separately in combination with exemestane and Hodgkin's lymphoma as a single agent. Entinostat is also being studied in advanced non-small-cell lung cancer and in advanced colorectal cancer in combination with azacitidine under a Cooperative Research and Development Agreement (CRADA) with the NIH.

Research has shown that HDACs are involved in the expression of various genes, such as the estrogen receptor, 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 overcome tumor resistance to targeted 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.