Syndax Pharmaceuticals’ Entinostat Plus Erlotinib Improves Survival in Select NSCLC Patients

--Phase 2 data to be presented at 2010 Chicago Multidisciplinary Symposium in Thoracic Oncology--

Waltham, Mass. – December 9, 2010 – Syndax Pharmaceuticals, Inc., a clinical-stage epigenetics oncology company, announces clinical results from ENCORE 401, a double-blind, placebo-controlled phase 2 trial, in patients with advanced non-small cell lung cancer (NSCLC). The results show that there was a survival advantage in the subset of patients with elevated E-cadherin (a molecular marker of epithelial tumors) receiving entinostat in combination with erlotinib (Tarceva®).

“The data suggest that NSCLC patients with elevated E-cadherin do better when treated with entinostat and erlotinib than erlotinib alone,” said principal investigator Robert M. Jotte, M.D., Ph.D., director of thoracic oncology at Rocky Mountain Cancer Center Midtown Division in Denver and Developmental Co-Chair of US Oncology Lung Committee. “In the patients with elevated E-cadherin, the median survival was 9.4 months in those treated with erlotinib plus entinostat compared to 5.4 months in the patients treated with erlotinib plus placebo. Since patients with elevated E-cadherin represent approximately 40 percent of the overall non-small cell lung cancer population, this potentially is an important new treatment option that could improve outcomes for patients with NSCLC.”

Results from ENCORE 401 will be presented tomorrow, Friday, December 10, 2010, in an oral presentation at the ASTRO 2010 Chicago Multidisciplinary Symposium in Thoracic Oncology. This symposium is co-sponsored by the American Society for Radiation Oncology (ASTRO), the American Society of Clinical Oncology (ASCO), the International Association for the Study of Lung Cancer (IASLC) and The University of Chicago.

“Using a biomarker to select patients based on the tumor biology can improve patient outcomes versus treating an unselected patient population,” said Fred Hirsch, M.D., Ph.D., professor of medicine and pathology at the University of Colorado Health Sciences Center. “Restoring E-cadherin expression has been shown preclinically to increase sensitivity to EGFR inhibitors thereby restoring sensitivity to the standard of care treatment. E-cadherin, which can be measured easily in tumors, is therefore a potentially relevant clinical biomarker to select patients for treatment with erlotinib plus entinostat.”

The primary endpoint of the study was four-month progression free survival rate with progression free survival (PFS) and overall survival (OS) as additional endpoints. In the unselected patient population made up of 132 evaluable patients, entinostat plus erlotinib appeared comparable in terms of PFS and survival. In the E-cadherin high sub-group (N = 26), entinostat plus erlotinib was associated with improved PFS and survival. The median PFS for the patients in the E-cadherin high
group treated with entinostat and erlotinib was 3.7 months vs. 1.9 months for the group treated with placebo and erlotinib (Hazard ratio 0.55) with a p-value of 0.19. The median survival was 9.4 months in the subgroup treated with entinostat and erlotinib vs. 5.4 months for those treated with placebo and erlotinib (Hazard ratio 0.36) with a p-value of 0.03.

Entinostat/erlotinib was tolerable with no unexpected adverse events and a manageable safety profile.

“Directing therapy based on the individual biology of a patient’s tumor is finally driving better outcomes for patients with lung cancer,” said Joanna Horobin, M.D., president and chief executive officer of Syndax. “Having seen improvement in PFS and overall survival in patients with tumors expressing high levels of e-cadherin who received entinostat and erlotinib, we now have a clear path forward. We look to add to treatment options as we evaluate entinostat with erlotinib in further randomized studies to be initiated next year in a selected patient population of NSCLC patients with high levels of E-cadherin.”

The abstract “Molecular Analysis Identifies A Subset Of Non-small Cell Lung Cancer Patients With Differential Sensitivity To Histone Deacetylase Inhibitor (hdaci) / Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor (egfr-tki) Treatment” was accepted as a late-breaker and will be given as an oral presentation at a scientific session at 2:15 p.m. on Friday, December 10, 2010.

For more Information regarding the presentation please visit [http://www.thoracicsymposium.org/](http://www.thoracicsymposium.org/).

**About Non-Small Cell Lung Cancer (NSCLC)**

Non-small cell lung cancer, a disease in which malignant cells form in the tissues of the lungs, is the most common type of lung cancer. The three main types of non-small cell lung cancer are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma. Each year there are more than 200,000 cases of newly diagnosed advanced NSCLC. About 60% of patients present with advanced NSCLC, meaning it has spread beyond the lung, when they are seen by a doctor. The five-year survival rate is less than 10 percent for patients with advanced NSCLC.

**About Entinostat**

Entinostat is an orally bioavailable, highly selective, class I histone deacetylase (HDAC) inhibitor with a long half-life that allows for weekly or every-other-week dosing. In addition to ENCORE 401, entinostat is being studied in numerous phase 2 clinical trials including a trial in advanced breast cancer patients in combination with aromatase inhibitors and in a Hodgkin’s lymphoma trial as a single agent. Under a Cooperative Research and Development Agreement (CRADA) with the NCI, Entinostat also is being studied in multiple types of solid tumors and hematologic cancers.
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 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, 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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