Syndax Pharmaceuticals Announces Entinostat Data from Two Lung Cancer Clinical Trials at Upcoming World Lung Conference

-- Entinostat positioned to advance toward phase 3 program in advanced NSCLC --

Waltham, Mass. – June 27, 2011 – Syndax Pharmaceuticals, Inc., a clinical-stage epigenetics oncology company, today announced that data from two entinostat clinical trials both based on tumor reprogramming will be presented at the International Association for the Study of Lung Cancer's (IASLC) 14th World Conference on Lung Cancer meeting (www.2011worldlungcancer.org) July 3 to 7 in Amsterdam, The Netherlands.

"The data presentations from both lung cancer programs at the World Conference on Lung Cancer demonstrate the clinical progress we are making with entinostat as we advance toward phase three," said Joanna Horobin, president and chief executive officer of Syndax. "The results add to the growing body of evidence that entinostat can maintain and restore sensitivity to standard of care treatments in distinct subpopulations of patients. Having completed placebo-controlled phase 2 clinical trials in both lung and breast cancer, we are actively planning the final stage of development."

Entinostat and Erlotinib (Tarceva®)

Targeted therapies such as epidermal growth factor receptor inhibitors (EGFRi) have greatly improved the treatment of those non small cell lung cancer (NSCLC) patients that harbor the appropriate targets. However, other patients experience less benefit due in part to epigenetic changes in the tumor which reduce the sensitivity to EGFRi such as erlotinib. Entinostat has been shown to delay the emergence of erlotinib resistance by maintaining a sensitive tumor phenotype.[1] In other preclinical studies entinostat was shown to synergize with certain EGFRi's to enhance gene re-expression and inhibit cancer cell growth.[2] ENCORE-401, a double-blind, placebo-controlled phase 2 trial of erlotinib with and without entinostat in patients with advanced NSCLC was conducted to confirm the preclinical findings.

"The patients with advanced NSCLC and elevated levels of tumor e-cadherin at the time of initial diagnosis seemed to do better when treated with erlotinib and entinostat than those treated with erlotinib alone," said Fred R. Hirsch, M.D., Ph.D., Professor of Medicine and Pathology, University of Colorado Health Sciences Center. "Increasingly we are seeing the importance of biomarkers in predicting patient outcomes in lung cancer. Patients with tumors with elevated e-cadherin levels represent about 40 percent of the population, demonstrating e-cadherin is a potentially relevant clinical biomarker to select patients for treatment with erlotinib plus entinostat."

The following poster and oral presentation on the entinostat and erlotinib combination will be presented Wednesday, July 6 at the World Conference on Lung Cancer:

Title:	Analysis of cross-over portion of ENCORE-401, a randomized, double-blind, placebo-controlled phase 2 study of erlotinib with and without entinostat, a class 1 isoform selective histone deacetylase inhibitor (HDAC) in patients with advanced non-small cell lung cancer
Time:	12:15 PM – 2:15 PM
Session info:	P3.220
Room:	Exhibition Hall

Title:	Biomarker analysis of a randomized, double-blind, placebo-controlled phase 2 study of erlotinib with and without entinostat, a class 1 isoform selective histone deacetylase inhibitor (HDAC) in patients with advanced non-small cell lung cancer (NSCLC; ENCORE-401)
Time:	2:30 PM - 4:00 PM*
Session info:	Mini Oral Session, MO15.04
Room:	G104

* This presentation also will be the subject of an e-poster on the same day from 12:15 to 2:15.

Entinostat and 5-Azacitidine (Vidaza®)

Syndax and the National Cancer Institute (NCI) are using a dual epigenetic therapy approach to treating advanced lung cancer. It has been shown that epigenetic gene silencing mediated by DNA methylation and histone deaceylation is a key contributor to lung carcinogenesis. In a phase 2 clinical trial patients with recurrent, metastatic NSCLC having received at least one prior chemotherapy regimen were given 5-azacitidine (5AC) and entinostat. The trial showed that the combination of 5AC and entinostat is generally well tolerated and demonstrated major objective responses. Through biomarker analyses investigators identified a subset of patients where a greater clinical benefit was observed. This subset consisted of patients with more methylated alleles and who experienced decreasing methylation during the first cycle of entinostat and 5AC. This study is being sponsored by the NCI under a Cooperative Research and Development Agreement with Syndax.

"These exciting biomarker data provide new insight and a path forward to selecting patients with NSCLC for whom the entinostat and 5AC combination may be particularly beneficial,"added Dr. Horobin.

The data from the entinostat and 5AC combination will be presented at the World Conference on Lung Cancer:

Date:	Tuesday, July 5:
Time:	12:15 PM - 2:00 PM
Session info:	P2.257
Title:	Biomarker Development for a Phase II Study of Combination Epigenetic Therapy in Advanced Non-Small Cell Lung Cancer (NSCLC)
Room:	Exhibition Hall

About Entinostat

Syndax's lead product entinostat has been studied in more than 600 cancer patients where objective tumor responses have been observed in both solid and hematologic malignancies. Entinostat's established safety profile as both a single agent and in combination with a number of commercially available targeted therapies differentiates it from other histone deacetylase (HDAC) inhibitors. Having shown potential in breast and lung cancer, entinostat is moving toward pivotal clinical testing. It is a novel inhibitor of class I histone deacetylases, key enzymes that alter the structure of chromatin to control gene expression. This aberrant gene expression can result in reversible, epigenetically-based drug tolerance. Designed to selectively target the HDAC isoforms most relevant to the biology of tumors, entinostat can normalize dysregulated gene expression in cancer cells.

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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1. Sharma et al 2010 "A chromatin-mediated reversible drug-tolerant state in cancer cell subpopulations," Cell 141(1):69-80.
2. Witta et al, 2006 "Restoring E-cadherin expression increases sensitivity to epidermal growth factor receptor inhibitors in lung cancer cell lines," Cancer Research 66(2):944-50

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