



**Syndax Pharmaceuticals Announces Publication of Entinostat Phase 2 Clinical Trial Data in *Journal of Clinical Oncology***

***--Entinostat Plus Erlotinib Demonstrated Improved Survival in Select NSCLC Patients--***

Waltham, Mass. – April 30, 2012 – Syndax Pharmaceuticals, Inc., a late-stage oncology company focused on the clinical development of epigenetic therapies in solid tumors, announced that [previously reported results from ENCORE 401](#), a randomized, placebo controlled Phase 2 study of erlotinib with or without entinostat in advanced non-small cell lung cancer patients were published in the *Journal of Clinical Oncology* (JCO). The article entitled, “Randomized Phase II Trial of Erlotinib With and Without Entinostat in Advanced Non-Small Cell Lung Cancer Patients Who Progressed on Prior Chemotherapy” was featured in the April 12<sup>th</sup> JCO [online](#) edition of the journal.

The study was based on preclinical observations that entinostat can reverse and/or delay the emergence of epigenetically driven resistance to epidermal growth factor receptor inhibitors such as erlotinib in NSCLC tumors. The results from ENCORE 401 confirmed the preclinical findings and demonstrated an improved overall survival in the subset of NSCLC patients with tumors expressing elevated levels of E-cadherin (a molecular marker of epithelial tumors and EGFRi sensitivity). In an accompanying JCO *Understanding the Pathways* article the authors note “The clinical data thus partially recapitulate the laboratory work, suggesting that HDAC inhibitors can preserve a pre-existing epithelial phenotype and that such patients will demonstrate sensitivity to erlotinib for a longer period of time.”

Based on these findings Syndax recently partnered with [Ventana Medical Systems](#) to develop an E-cadherin companion diagnostic assay to select those NSCLC patients with elevated E-cadherin levels in their tumor cells for treatment with erlotinib and entinostat in the confirmatory study.

“The positive results from this trial, while preliminary, offer exciting possibilities for the future,” said Paul A. Bunn, Jr, MD, professor, James Dudley Chair in cancer research, School of Medicine, division of medical oncology, University of Colorado. “The use of E-cadherin appears to be an excellent predictive biomarker to select patients, especially those with wild type EGFR for this combination therapy. For these patients, the combination may provide an important improvement in the small benefit of erlotinib therapy. Patients with EGFR mutations usually have high E-cadherin levels and may also have great benefit from this combination with a higher response and longer duration of remission. Of course, further studies in both of these groups of patients will be necessary to confirm these observations.”

“The data published in JCO adds to the growing body of clinical data supporting the promise for entinostat and our continued development of epigenetic strategies to overcome resistance to standard of care agents in solid tumors,” said Joanna Horobin, MD, president of Syndax. “Given this NSCLC data plus our recently reported positive data with entinostat in advanced breast cancer patients, we are eager to initiate our pivotal programs and ultimately provide new treatment options based on a backbone of epigenetic therapy to cancer patients.”

### **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**

Syndax holds worldwide rights to entinostat, an oral, highly selective histone deacetylase (HDAC) inhibitor, which inhibits the cancer-relevant class 1 HDAC enzymes that contribute to epigenetic alterations driving cancer growth and drug tolerance. Entinostat's unique pharmacokinetic properties, convenient oral dosing and HDAC selectivity, maximize the opportunity to safely combine with and potentially extend the benefit of proven cancer therapies. Entinostat has been studied in more than 600 cancer patients with clinical activity in solid tumors 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 erlotinib (ENCORE 401) in non-small cell lung cancer. Results from the ENCORE clinical program have provided the basis for moving entinostat into pivotal, phase 3 testing across a platform of solid tumor indications. NCI and Syndax are collaborating on the development of entinostat under a Cooperative Research and Development Agreement.

### **About Syndax**

Syndax is a late-stage oncology company initiating pivotal programs in solid tumors based on employing epigenetic strategies to overcome the problem of resistance in oncology care. The company is supported by top venture capitalists and led by industry experts developing treatments for large markets including metastatic breast and lung cancer. 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](http://www.syndax.com).

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