

Syndax Pharmaceuticals Announces Entinostat Enhanced Activity of Cancer Immunotherapies in Renal and Prostate Cancer Models

- Data highlights novel immunomodulatory effects of entinostat -

Waltham, Mass. – February 8, 2012 – Syndax Pharmaceuticals, Inc., a clinical-stage epigenetics oncology company, announced that scientists at Roswell Park Cancer Institute have demonstrated that entinostat, Syndax's novel, oral small molecule inhibitor of class I histone deacetylases, has novel immunomodulatory properties that contribute to the enhanced activity of cancer immunotherapies in models of renal and prostate cancer. The results were published in PLoS ONE in an article titled, "Class I Histone Deacetylase Inhibitor Entinostat Suppresses Regulatory T Cells and Enhances Immunotherapies in Renal and Prostate Cancer Models."

"The results demonstrate a novel immunomodulatory effect of entinostat and provide a rationale for the clinical testing of entinostat to enhance cancer immunotherapy," said Roberto Pili, MD, professor of oncology, chief, genitourinary section and co-leader, genitourinary program, department of medicine, Roswell Park Cancer Institute. "We are interested in testing whether entinostat could improve the benefit seen with immunotherapies in the advanced disease population where oncology treaments are limited."

The results, published in the January 23rd issue of PLOS, show that entinostat inhibits the function of T regulatory cells that are involved in suppressing the anti-tumor activity of immune based therapies. Importantly entinostat maintained the activity of the T effector cell population.

"This exciting pre-clinical data provides new information about entinostat's mechanism of action, expanding the potential for entinostat in new combinations in solid tumors," said Joanna Horobin, MD, president and chief executive officer of Syndax. "Because of collaborations like this one with the Roswell Park Cancer Institute, we are able to continue to investigate new combinations that could ultimately change the clinical outcomes for oncology patients who need new treatment options."

A proof-of-concept clinical study testing this hypothesis is underway with entinostat combined with interleukin-2 in renal cell cancer. Additional studies in combination with recently approved immunotherapies are planned. Entinostat has shown effect in phase 2 clinical testing in other solid tumors including with the aromatase inhibitor exemestane in advanced breast cancer and with the epidermal growth factor receptor inhibitor erlotinib in advanced lung cancer.

About Entinostat

Syndax's lead product entinostat is a novel, oral small molecule inhibitor of class I histone deacetylases, key enzymes that alter the structure of chromatin to control gene expression. Entinostat is differentiated from other members of the class through its unique selectivity profile, pharmacokinetic properties and safety profile. Entinostat has been studied in more than 600 cancer patients where objective tumor responses have been observed in both solid 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 in non-small cell lung cancer (ENCORE 401). Results from the ENCORE clinical program have provided the basis for moving entinostat into pivotal, phase 3 testing across a platform of breast and lung cancer indications.

About Syndax

Syndax Pharmaceuticals, Inc. is a Waltham, MA-based, late-stage, oncology-focused pharmaceutical company. The company 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. Syndax has worldwide rights to develop and commercialize entinostat which has shown promise in <u>randomized clinical trials</u> in solid tumors and in phase 2 clinical trials in Hodgkin's lymphoma. Syndax is backed by top-tier venture capital firms Domain Associates, MPM Capital, Avalon, Pappas and Forward Ventures. Formed in 2005, Syndax's intellectual property is based on work from scientific founder Ronald Evans, Ph.D., recipient of the 2012 Wolf Prize in Medicine, 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.

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