Syndax Pharmaceuticals Announces Start of Phase 1/2 Study of Entinostat in Combination with Lapatinib in HER2-Positive Metastatic Breast Cancer

Waltham, Mass. – April 9, 2012 – Syndax Pharmaceuticals, Inc., a clinical-stage epigenetics oncology company, announced that investigators at The University of Texas MD Anderson Cancer Center have initiated a multi-center phase 1/2 study combining Syndax's lead product entinostat with lapatinib ditosylate (Tykerb) in patients with locally recurrent or distant relapsed metastatic breast cancer previously treated with trastuzumab (Herceptin®). The study sponsored by MD Anderson is being conducted in collaboration with the National Cancer Institute (NCI) Division of Cancer Treatment and Diagnosis and Glaxo Smith Kline (GSK). Preclinical data has demonstrated that entinostat, a novel, selective histone deacetylase inhibitor can overcome acquired resistance to HER2 targeted therapies when combined with lapatinib.

"Based on preclinical work conducted by Syndax's collaborators, GSK scientists and our own laboratory, we believe entinostat may be effective in tackling the resistance pathways that contribute to the reduced efficacy of HER2-targeted agents in breast cancer patients progressing on such therapies," said Naoto T. Ueno, MD, PhD, FACP, section chief, translational breast cancer research, department of breast medical oncology, MD Anderson Cancer Center and principal investigator. "With the data we have generated, we are particularly excited to test this combination in patients with inflammatory breast cancer, a subset of breast cancer often expressing HER2 for whom there are few effective treatment options.

The phase 1 portion of the study will characterize the safety profile of the combination and identify the appropriate dosing regimen to be used in the phase 2 portion. Translational studies will provide valuable insight into the mechanism of action for the combination in tumor cells while potentially identifying biomarkers for patient selection in subsequent studies.

"This study represents our continued commitment to work with the NCI and our industry and academic collaborators to expand the ENCORE (ENtinostat Combinations Overcoming REsistance) platform aimed at overcoming resistance to targeted therapies in breast cancer and other solid tumors" said Joanna Horobin, MD, president and chief executive officer of Syndax. "With our recently reported positive data in ENCORE 301 targeting ER+ breast cancer and the NCI sponsored study NCT01234532 combining entinostat with Arimidex in ER-, PR-, HER2- triple negative breast cancer we are pleased to be in a position to provide proof-of-concept clinical data across all segments of breast 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 breast and lung cancer 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 in pivotal, phase 3 testing across a platform of breast and lung cancer indications. NCI and Syndax are collaborating on the development of entinostat under a Cooperative Research and Development Agreement.

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 randomized clinical trials in breast and lung cancer 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 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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