

# Syndax Pharmaceuticals Secures \$26.6 Million Series B Financing for Advancement of Epigenetic Therapies for Treatment-Resistant Cancers

# Company Prepares for Pivotal Phase 3 Study of Entinostat, Most Advanced HDAC Inhibitor in Development for ER+ Metastatic Breast Cancer

WALTHAM, Mass., Aug. 27, 2013 — <u>Syndax Pharmaceuticals Inc</u>., which is developing epigenetic therapies for treatment-resistant cancers, today announced it has secured a \$26.6 million Series B financing. Participating investors included Domain Associates, MPM Capital, Forward Ventures and RusnanoMedInvest (RMI).

Syndax plans to use the proceeds to continue advancement of its late-stage pipeline of epigenetic-based combination therapies for treatment-resistant cancers, including activities in preparation for an NDA-enabling Phase 3 study of entinostat in metastatic breast cancer. The study is currently being developed by the ECOG-ACRIN Cancer Research Group, which would conduct the study under the sponsorship of the Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI).

"Entinostat represents the most advanced clinical program of an epigenetic therapy in solid tumors," said Arlene M. Morris, Syndax's chief executive officer. "We have a unique opportunity to help a patient population where safe and effective treatments capable of extending survival are needed desperately. The Series B financing enables us to continue to advance entinostat toward registration, where we believe the opportunity in breast cancer and lung cancer alone exceeds \$2 billion."

In the completed Phase 2 ENCORE 301 study, entinostat was shown to extend both progression-free survival and overall survival when added to exemestane in postmenopausal women with estrogen receptor-positive (ER+) metastatic breast cancer whose cancer had progressed after treatment with a nonsteroidal aromatase inhibitor. In addition, a potential pharmacodynamic biomarker identified in a subset of patients with ER+ tumors was associated with greater progression-free survival.

## **About Entinostat**

Entinostat, Syndax's lead product candidate, has been studied in more than 800 cancer patients where objective tumor responses have been observed in both solid and hematologic malignancies. Entinostat's established safety and efficacy profile as both a single agent and in combination with a number of commercially available targeted therapies differentiates it from other histone deacetylase inhibitors (HDACi). Having demonstrated promising clinical results in

breast and lung cancer, entinostat is moving toward pivotal clinical testing. It is an oral, 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, thereby restoring sensitivity to targeted therapy. Entinostat is the first HDACi with positive results in a randomized Phase 2 study in breast cancer and is the only HDACi in late-stage development for this indication.

# **About Syndax Pharmaceuticals**

Syndax is focused on employing epigenetic strategies to overcome the problem of resistance in oncology care in solid tumors. The company holds worldwide rights to entinostat, an oral, highly selective histone deacetylase (HDAC) inhibitor in late-stage clinical development for the treatment of advanced breast cancer and lung cancer. A randomized, placebo-controlled Phase 2 study of entinostat in combination with aromatase inhibitors in breast cancer (ENCORE 301) demonstrated an improvement in both progression-free survival and overall survival, providing the basis for the evaluation of entinostat in pivotal Phase 3 testing in metastatic breast cancer. Entinostat also demonstrated promising results in a subset of non-small cell lung cancer patients when given in combination with the EGFR-TKI erlotinib (ENCORE 401). NCI and Syndax are collaborating on the development of entinostat under a Cooperative Research and Development Agreement aimed at improving survival in advanced, hard-to-treat cancers.

For more information, visit <u>www.syndax.com</u>.

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