

Press Release

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First Patient Enrolled in ECOG-ACRIN Phase III Trial of Syndax's Entinostat

Entinostat is being investigated in patients with advanced hormone receptor-positive breast cancer by the ECOG-ACRIN Cancer Research Group in trial E2112.

PHILADELPHIA, Pa. and WALTHAM, Mass., June 30, 2014 – The ECOG-ACRIN Cancer Research Group and Syndax Pharmaceuticals Inc. announced today enrollment of the first patient in E2112, a randomized phase III clinical trial of Syndax's histone deacetylase (HDAC) inhibitor, entinostat, for the treatment of patients with advanced breast cancer. The trial is evaluating whether the addition of entinostat to endocrine therapy (exemestane, a steroidal aromatase inhibitor) improves progression-free survival and/or overall survival in men and postmenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative advanced breast cancer who have progressed following treatment with a non-steroidal aromatase inhibitor.

"Given that Syndax's previous randomized phase II trial, ENCORE 301, in a similar population, demonstrated improvements in both progression-free survival and overall survival, E2112 represents a very important phase III trial in breast cancer patients," said study lead investigator Roisin M. Connolly, MB, BCh, assistant professor of oncology, Johns Hopkins University, Baltimore, Md. "There continues to be a large unmet medical need for effective and well tolerated treatments for patients with advanced hormone receptor-positive breast cancer. We are hopeful that the overall survival benefit observed in ENCORE 301 will be replicated in E2112."

E2112 was designed and is being conducted by ECOG-ACRIN under the sponsorship of, and with funding support from, the National Cancer Institute (NCI). Syndax, the developer of entinostat, is supporting the trial under a Cooperative Research and Development Agreement with the NCI and a separate agreement with ECOG-ACRIN.

E2112 has an accrual goal of 600 patients. Recruitment to the trial will involve participation from ECOG-ACRIN, the Alliance for Clinical Trials in Oncology, NRG Oncology and SWOG—all network groups in the NCI National Clinical Trials Network that collaboratively conduct cancer research in adults.

Arlene M. Morris, chief executive officer of Syndax, added, "Our goal is to provide patients with advanced hormone receptor-positive breast cancer with a more effective treatment option than those currently available. We are excited that entinostat has achieved this important development milestone after being designated a Breakthrough Therapy by the Food and Drug Administration and we look forward to our ongoing collaboration with ECOG-ACRIN and the NCI. The design of E2112 provides for two primary endpoints, progression-free survival and overall survival, and we expect that either endpoint may serve as the basis for submitting a New Drug Application to the FDA, if data are positive. The trial is being conducted under a Special Protocol Assessment with the FDA."

About the ECOG-ACRIN Cancer Research Group

The ECOG-ACRIN Cancer Research Group is a multidisciplinary, membership-based scientific organization that designs and conducts biomarker-driven cancer research involving adults who have or are at risk of developing cancer. The Group was formed in May 2012 by a merger that combined the complementary strengths of the Eastern Cooperative Oncology Group (ECOG) in cancer therapy and the American College of Radiology Imaging Network (ACRIN) in cancer imaging. ECOG and ACRIN were two highly respected NCI-sponsored cancer cooperative groups. ECOG-ACRIN comprises nearly 650 member institutions in the United States and around the world. Approximately 6,000 physicians, translational scientists and associated research professionals from the member institutions are involved in Group research, which is organized into three scientific programs: Cancer Control and Outcomes, Therapeutic Studies and Biomarker Sciences. ECOG-ACRIN is supported primarily through NCI research grant funding, but also receives funding from private sector organizations through philanthropy and collaborations. It is headquartered in Philadelphia, Pa., as is PrECOG LLC, a not-for-profit company that partners with ECOG-ACRIN and industry to develop and conduct clinical trials in all areas of oncology. For more information, visit www.ecog-acrin.org or call 215.789.3631.

About Syndax Pharmaceuticals

Syndax is developing entinostat for the treatment of patients with therapy-resistant cancers. Entinostat is being developed to target resistance to current cancer therapies through an epigenetic mechanism and has been designated a Breakthrough Therapy by the FDA when used in combination with exemestane in HR+ advanced (locally advanced or metastatic) breast cancer. Entinostat is an oral, selective HDAC inhibitor that is being evaluated in combination with exemestane in a pivotal Phase 3 clinical study for the treatment of hormone receptor-positive metastatic breast cancer. Syndax holds rights to entinostat in all major markets.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements contained in this press release include statements about the results of the phase II trial and whether the E2112 trial will serve as a basis for filing an NDA. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance and involve a number of unknown risks, assumptions, uncertainties and factors that are beyond Syndax's control. All forward-looking statements are based on Syndax's expectations and assumptions as of the date of this press release. Actual results may differ materially from these forward-looking statements. Except as required by law, Syndax expressly disclaims any responsibility to update any forward-looking statement contained herein, whether as a result of new information, future events or otherwise.

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