ECOG-ACRIN Provides Syndax Pharmaceuticals With Results of Phase 3 E2112 Trial of Entinostat Plus Exemestane in Patients with HR+, HER2- Breast Cancer

May 21, 2020

WALTHAM, Mass., May 21, 2020 /PRNewswire/ -- Syndax Pharmaceuticals, Inc. (Nasdaq: SNDX) today announced receipt of the final results of E2112, the Phase 3 clinical trial conducted by ECOG-ACRIN Cancer Research Group (ECOG-ACRIN) and sponsored by the National Cancer Institute (NCI), that evaluated the investigational compound entinostat, Syndax's class I HDAC inhibitor, plus exemestane in patients with advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer who have progressed on a non-steroidal aromatase inhibitor. The trial did not achieve the primary endpoint of demonstrating a statistically significant overall survival (OS) benefit over hormone therapy alone.

"We're disappointed that the combination of entinostat and exemestane did not demonstrate a survival benefit in this historically difficult-to-treat patient population," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "On behalf of the entire Syndax team, we extend our sincerest gratitude to all the patients, their families and the investigators who participated in this important trial, as well as our colleagues at ECOG-ACRIN and the NCI. Based on these results, we will not be filing a New Drug Application with the U.S. Food and Drug Administration for metastatic breast cancer."

Dr. Morrison added, "We remain focused on advancing our broader portfolio, including our targeted therapy, SNDX-5613, an inhibitor of the Menin-MLL interaction, and axatilimab, our anti-CSF-1R monoclonal antibody. Later this year, we expect to present additional clinical data from the AUGMENT-101 trial of SNDX-5613 in adults with relapsed/refractory acute leukemias. Based on preclinical data reported to date, as well as recent Phase 1 results representing the first clinical evidence that inhibition of the Menin-MLL1 interaction can induce response in patients with genetically-defined acute leukemias, we believe SNDX-5613 has the potential to offer patients with both NPM1 mutant acute myeloid leukemia and MLL-r acute leukemias a much-needed, effective therapeutic option. We also anticipate the presentation of additional results from our ongoing Phase 1/2 trial of axatilimab in patients with chronic graft versus host disease in the fourth quarter of this year."

The E2112 trial was designed and conducted independently by ECOG-ACRIN under the sponsorship of the NCI, which is part of the National Institutes of Health. The double-blind, placebo-controlled trial randomized a total of 608 patients with HR+, HER2- advanced breast cancer to receive exemestane in combination with entinostat or placebo.

About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. The Company's pipeline includes SNDX-5613, a highly selective inhibitor of the Menin–MLL binding interaction, axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, and entinostat, a class I HDAC inhibitor. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

Syndax's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "believe" 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 based on Syndax's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, clinical development and scope of clinical trials and the reporting of clinical data for Syndax's product candidates, and the potential use of our product candidates to treat various cancer indications. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical trials, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, the COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity, failure of Syndax's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Other factors that may cause Syndax's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Syndax's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Syndax assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Investor Contact

Melissa Forst
Argot Partners
melissa@argotpartners.com
Tel 212.600.1902

Media Contact

Ted Held
GCI Health
ted.held@gcihealth.com
Tel 212.798.9842

SNDX-G

View original content:http://www.prnewswire.com/news-releases/ecog-acrin-provides-syndax-pharmaceuticals-with-results-of-phase-3-e2112-trial-of-entinostat-plus-exemestane-in-patients-with-hr-her2--breast-cancer-301063954.html

SOURCE Syndax Pharmaceuticals, Inc.