Syndax Announces Data from Pivotal AUGMENT-101 Trial of Revumenib in Relapsed/Refractory KMT2Ar Acute Leukemia Selected as Late-Breaking Presentation at the 65th ASH Annual Meeting

November 21, 2023

WALTHAM, Mass., Nov. 21, 2023 /PRNewswire/ -- Syndax Pharmaceuticals (Nasdaq: SNDX), a clinical-stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced that data from the pivotal trial of revumenib, the Company's highly selective, oral menin inhibitor, will be featured in a late-breaking presentation at the 65th American Society of Hematology (ASH) Annual Meeting being held December 9-12, 2023 in San Diego, California. A copy of the abstract is now available online via the ASH website at www.hematology.org.

"We are pleased the ASH program committee recognized AUGMENT-101 as a substantive study of high impact and selected it as a late-breaker presentation this year," said Michael A. Metzger, Chief Executive Officer. "We believe the AUGMENT-101 results continue to underscore revumenib's potential as a first- and best-in-class treatment option for patients with KMT2Ar and mNPM1 acute leukemias. We are excited to showcase revumenib's clinical profile both as a monotherapy and in combination at ASH ahead of a potential first FDA approval of revumenib in mid-2024."

Details of the presentation are as follows:

Abstract Number: LBA-5
Title: Revumenib Monotherapy in Patients with Relapsed/Refractory KMT2Ar Acute Leukemia: Topline Efficacy and Safety Results from the Pivotal AUGMENT-101 Phase 2 Study
Presenter: Ibrahim Aldoss, M.D.
Session Name: Late-Breaking Abstracts Session
Session Date: Tuesday, December 12, 2023
Session Time: 9:00 – 10:30 a.m. PT
Presentation Time: 10:00 a.m. PT

About the Pivotal Phase 2 Portion of the AUGMENT-101 Trial:

AUGMENT-101 is a Phase 1/2 open-label trial designed to evaluate the safety, tolerability, pharmacokinetics, and efficacy of orally administered revumenib. The Company previously announced positive topline data from the protocol-defined pooled analysis of the pivotal Phase 2 portion of the AUGMENT-101 trial in patients with relapsed/refractory (R/R) KMT2A-rearranged (KMT2Ar) acute leukemia. The trial met its primary endpoint with a complete remission (CR) or a CR with partial hematological recovery (CRh) rate of 23% at the interim analysis of the pooled KMT2Ar acute myeloid leukemia and acute lymphoid leukemia cohorts (p-value = 0.0036). Based on the Independent Data Monitoring Committee recommendation, the Company stopped the trial to further accrual in the KMT2Ar cohorts. Syndax has initiated the NDA submission for revumenib for the treatment of R/R KMT2Ar acute leukemia in adult and pediatric patients under the FDA's Real-time Oncology Review (RTOR) program and expects to complete the NDA submission by year-end 2023.

About Syndax

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Highlights of the Company's pipeline include revumenib, a highly selective inhibitor of the menin–KMT2A binding interaction, and axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

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," "could," "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, the reporting of clinical data for Syndax's product candidates, the potential submission of an NDA by year-end, and the potential use of our product candidates to treat various cancer indications and fibrotic diseases. 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; 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.

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