



Syndax Pharmaceuticals to Present Updated Data from Phase 1 Trial of Axatilimab in cGVHD During Oral Session at the 62nd ASH Annual Meeting

November 4, 2020

- Response rate of ~60% observed in patients following a median of five prior lines of treatment -

- Company to host conference call and webcast following oral presentation on Sunday, December 6, 2020 -

WALTHAM, Mass., Nov. 4, 2020 /PRNewswire/ -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced that updated data from the Company's Phase 1 trial of axatilimab, its anti-CSF-1R monoclonal antibody, in patients with chronic graft versus host disease (cGVHD) will be featured during an oral presentation at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition being held December 5 – 8, 2020 in a virtual format.

Key highlights of the abstract published today include:

- Objective responses observed in 7/12 patients with refractory disease and a median of five prior systemic therapies, including ibrutinib, ruxolitinib and belumosudil (KD-025)
- At time of abstract data cut-off, responses observed in joints/fascia (n=5/9), skin (n=3/8), eyes (n=3/10), esophagus (n=1/1) and mouth (n=1/7), with response data from additional organs to be described during the oral presentation
- Acceptable safety and tolerability in patients with advanced cGVHD; no treatment-related adverse events ≥ Grade 3 at the Phase 2 dose of 1 mg/kg every two weeks

The abstract can be viewed [here](#). The oral presentation will include data as of a more recent cutoff date.

"We are excited to see a high response rate in patients with multiple organ system involvement with axatilimab treatment in a highly refractory population of patients with cGVHD," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "To our knowledge, axatilimab is the only agent in development for cGVHD that specifically targets the monocyte-macrophage lineage, which plays a key role in the fibrotic disease process, and we believe this is why we are seeing such robust efficacy. The promising efficacy, combined with a well-tolerated safety profile, led us to advance axatilimab into a pivotal trial in cGVHD that we anticipate starting by the end of this year. We look forward to presenting updated findings from our Phase 1 trial at the ASH meeting in December."

In addition, the Company today announced that it plans to host a conference call featuring two experts in the science and treatment of cGVHD to discuss how axatilimab may fit in the current and evolving treatment landscape.

Oral Presentation Details:

Title: Phase 1 Study of Axatilimab (SNDX-6352), a CSF-1R Humanized Antibody, For Chronic Graft-Versus-Host Disease after 2 or More Lines of Systemic Treatment

Presenter: Mukta Arora, M.D., M.S., University of Minnesota

Session Name: 722. Clinical Allogeneic Transplantation; Acute and Chronic GvHD, Immune Reconstitution: Phase I and II Trials

Session Date: Sunday, December 6, 2020

Session Time: 9:30 a.m. - 11:00 a.m. PT (12:30 p.m. – 2:00 p.m. ET)

Presentation Time: 10:45 a.m. PT (1:45 p.m. ET)

Abstract Number: 358

Conference Call and Webcast Details:

The conference call and webcast, which will take place on Sunday, December 6, 2020 at 2:00 p.m. ET, will feature lead author of the ASH presentation, Mukta Arora, M.D., M.S., Professor of Medicine, Division of Hematology, Oncology and Transplantation at the University of Minnesota Medical School, and co-author, Geoffrey Hill, M.D., José Carreras/E. Donnell Thomas Endowed Chair for Cancer Research and Director of The Immunotherapy Integrated Research Center at Fred Hutchinson Cancer Research Center. The live audio webcast and accompanying slides may be accessed through the Events & Presentations page in the Investors section of the Company's website at www.syndax.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 8698086

Domestic Dial-in Number: (855) 251-6663

International Dial-in Number: (281) 542-4259

Live webcast: <https://edge.media-server.com/mmc/p/ddupdb6>

For those unable to participate in the live conference call or webcast, a replay will be available on the Investors section of the Company's website, www.syndax.com.

About Chronic Graft Versus Host Disease

Chronic graft versus host disease (cGVHD), an immune response of the donor-derived hematopoietic cells against recipient tissues, is a serious, potentially life-threatening complication of allogeneic hematopoietic stem cell transplantation (HSCT) which can last for years. cGVHD is estimated to develop in approximately 40% of transplant recipients, and affects approximately 14,000 patients in the U.S.^{1,2} cGVHD typically manifests across multiple organ systems, with the skin and mucosa being commonly involved, and is characterized by the development of fibrotic tissue.³

About Axatilimab

Axatilimab is an investigational monoclonal antibody that targets colony stimulating factor-1 receptor, or CSF-1R, a cell surface protein thought to control the survival and function of monocytes and macrophages. In pre-clinical models, inhibition of signaling through the CSF-1 receptor has been shown to reduce the number of disease-mediating macrophages along with their monocyte precursors, and block the development of cutaneous and pulmonary cGVHD. Axatilimab is currently being evaluated in a Phase 1/2 clinical trial in patients with cGVHD, and to date has demonstrated compelling clinical activity and a well-tolerated safety profile. Syndax plans to commence a pivotal trial, AGAVE-201, by the end of 2020.

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.

References

1. SmartAnalyst 2020 SmartImmunology Insights chronic GVHD report.
2. Bachier, CR. et al. ASH annual meeting 2019; abstract #2109 Epidemiology and Real-World Treatment of Chronic Graft-Versus-Host Disease Post Allogeneic Hematopoietic Cell Transplantation: A U.S. Claims Analysis
3. Kantar 2020 GVHD Expert Interviews N=32 interviews

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 View original content: <http://www.prnewswire.com/news-releases/syndax-pharmaceuticals-to-present-updated-data-from-phase-1-trial-of-axatilimab-in-cgvhd-during-oral-session-at-the-62nd-ash-annual-meeting-301166608.html>

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