Syndax Pharmaceuticals and Incyte Announce Global Collaboration to Develop and Commercialize Axatilimab for Chronic Graft-Versus-Host Disease and Other Fibrotic Diseases

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– Syndax to receive $152 million in cash ($117 million upfront plus a $35 million equity investment), with potential for $450 million in additional milestone payments; 50:50 profit share in the U.S. and double-digit royalties on ex-U.S. sales –

– The two companies expect to expand development of axatilimab in chronic graft-versus-host disease (cGVHD) with additional monotherapy and combination trials planned in 2022 –

– Syndax to commence Phase 2 proof of concept trial in idiopathic pulmonary fibrosis (IPF) in early 2022 –

– Incyte to lead U.S. and global commercial activities; Syndax retains option to co-promote in the U.S. –

– Syndax to host conference call today at 8:00 a.m. ET; Incyte to host conference call today at 10:00 a.m. ET –

WALTHAM, Mass. and WILMINGTON, Del., September 27, 2021 (PRNEWSWIRE) – Syndax Pharmaceuticals, Inc. (Nasdaq: SNDX) and Incyte (Nasdaq: INCY) announced today that they have entered into an exclusive worldwide collaboration and license agreement to develop and commercialize axatilimab, Syndax's anti-CSF-1R monoclonal antibody.

"This partnership has the potential to significantly expand and maximize the axatilimab program across multiple lines of treatment in chronic graft-versus-host Disease (cGVHD), as well as additional indications in which the monocyte-macrophage lineage plays a vital role in the fibrotic disease process, such as idiopathic pulmonary fibrosis (IPF)," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "Incyte is a proven leader in the development and commercialization of many important innovative therapies, including a treatment for GVHD. We are thrilled to be working alongside this talented and determined team to combine our expertise as we strive to provide new treatment options for patients in desperate need of effective interventions."

"We are excited to partner with Syndax and for the opportunity to bring another potential treatment to patients with life-threatening conditions, like GVHD," said Hervé Hoppenot, Chief Executive Officer of Incyte. "Collaborations between companies like Incyte and Syndax, who are both dedicated to scientific advancement, contribute to the development of new innovative medicines that may benefit patient communities around the world."

Syndax and Incyte are seeking to develop axatilimab as a backbone therapy for patients with cGVHD as well as in additional immune-mediated diseases where CSF-1R-dependent monocytes and macrophages are believed to contribute to organ fibrosis. Syndax recently completed a Phase 1/2 trial of axatilimab in patients with cGVHD. Data from the Phase 1 portion of the trial highlighting the tolerability and high response rate of axatilimab in cGVHD patients refractory to multiple therapeutic agents were reported during an oral presentation at the American Society of Hematology Annual Meeting in December 2020. Updated results from the Phase 1 portion and preliminary results from the Phase 2 expansion portion of the study, which evaluated 1 mg/kg of axatilimab every two weeks, are expected to be presented at a medical meeting in the fourth quarter of 2021.

Enrollment continues in the ongoing global pivotal Phase 2 AGAVE-201 trial of axatilimab monotherapy in patients with cGVHD, with topline data expected in 2023. The companies also plan to initiate additional trials of axatilimab in patients with cGVHD in 2022, including a Phase 2 trial in combination with a JAK inhibitor in patients with steroid-refractory cGVHD. Beyond cGVHD, Syndax plans to commence a Phase 2 proof of concept trial of axatilimab early next year in patients with IPF, a serious, life-limiting orphan disease for which axatilimab could represent a much-needed treatment option with a novel mechanism of action.

Terms of the Collaboration

Under the terms of the agreement, Incyte will lead global commercial activities for axatilimab across all indications. The companies will participate in a 50:50 profit share in the U.S., and Syndax will receive double-digit royalties on sales outside of the U.S. Syndax will retain the option to co-promote axatilimab for any approved indications in the U.S. In connection with the agreement, Syndax will receive an upfront payment of $117 million plus a $35 million equity investment, which will be purchased at $24.62 per share, a 30% premium to the volume weighted average price over the 10 days prior to September 24, 2021. Syndax will also be eligible to receive up to an additional $450 million in potential regulatory, development and commercial milestone payments.

The companies will share development costs associated with global and U.S.-specific trials for all agreed upon trials at a rate of 55% (Incyte) and 45% (Syndax), with Incyte responsible for 100% of future development costs for trials that are specific to ex-U.S. countries. Syndax will fund the initial development of axatilimab in IPF and Incyte will have the option to co-fund late-stage development for this indication.

The agreement between Syndax and Incyte, including the upfront payment and equity investment, is subject to clearance by the U.S. antitrust authorities under the Hart-Scott-Rodino Act and will become effective as soon as these conditions have been met.

Goldman Sachs & Co. LLC is acting as the exclusive financial advisor to Syndax.

Syndax Conference Call and Webcast

In connection with this announcement, Syndax's management team will host a conference call and live audio webcast at 8:00 a.m. ET today, September 27, 2021.

The live audio webcast may be accessed through the Events & Presentations page in the Investors section of Syndax's website at www.syndax.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 9875536
Domestic Dial-in Number: (855) 251-6663
International Dial-in Number: (281) 542-4259
Live webcast: https://edge.media-server.com/mmc/p/7qge5abd

For those unable to participate in the conference call or webcast, a replay will be available for 30 days on the Investors section of Syndax's website, www.syndax.com.

Incyte Conference Call and Webcast

Incyte will also host an analyst and investor conference call and webcast at 10:00 a.m. ET to discuss today's news and the Company's recent product approval in chronic GVHD. The live and archived webcast will be available via investor.incyte.com.

To access the conference call, please dial 877-407-3042 for domestic callers or +1-201-389-0864 for international callers (conference identification number 13723505).

If you are unable to participate, a replay will be available for 90 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is +1-201-612-7415 (conference identification number 13723505).

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. Chronic GVHD is estimated to develop in approximately 40% of transplant recipients, and affects approximately 14,000 patients in the U.S.[1,2] Chronic GVHD typically manifests across multiple organ systems, with skin and mucosa being commonly involved, and is characterized by the development of fibrotic tissue.[3]

About Idiopathic Pulmonary Fibrosis

Idiopathic Pulmonary Fibrosis (IPF) is a serious, life-limiting chronic lung disease characterized by fibrosis and scarring of lung tissue with a median survival of 3-5 years after diagnosis. Patients with IPF experience debilitating symptoms including progressive shortness of breath, particularly with exertion, chronic cough, fatigue, weakness, and chest discomfort. Currently approved drugs slow but do not halt disease progression and the only curative therapy is lung transplant, which is an option for less than 5% of patients. Estimates indicate that IPF could affect approximately 150,000 patients in the U.S. and approximately 260,000 patients across the seven major pharmaceutical markets (U.S., Japan, UK, Spain, Germany, Italy, and France).[4]

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, which has been shown to play a key role in the fibrotic disease process underlying diseases, such as chronic graft-versus-host disease (cGVHD) and idiopathic pulmonary fibrosis (IPF). Axatilimab data has demonstrated deep, durable responses and multiorgan clinical benefit in patients with cGVHD refractory to multiple therapeutic agents, and is currently being evaluated in the global pivotal Phase 2 AGAVE-201 trial in patients with cGVHD. Axatilimab was granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of patients with cGVHD and IPF. Axatilimab is being developed under an exclusive worldwide license from UCB entered into between Syndax and UCB in 2016.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development, and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

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.

Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether or when axatilimab might provide a successful treatment option for patients with steroid-refractory cGVHD or other diseases; Incyte's plans to develop and commercialize axatilimab, either as a monotherapy or in combination with other therapies; and Incyte's expectations for its collaboration with Syndax, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on Incyte's clinical trials supply chain and other third-party providers and development and discovery operations; determinations made by the U.S. antitrust authorities, the FDA or other regulatory authorities; Incyte's dependence on its relationships with its collaboration partners; the efficacy or safety of the Incyte's products and the products of Incyte's collaboration partners; the

acceptance of the Company's products and the products of the Incyte's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended June 30, 2021. Incyte disclaims any intent or obligation to update these forward-looking statements.

Syndax 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 regarding whether or when axatilimab might provide a successful treatment option for patients with steroid-refractory cGVHD or other diseases; Syndax's plans to develop and commercialize axatilimab, either as a monotherapy or in combination with other therapies; Syndax's expectations for its collaboration with Incyte; the design, progress, timing, clinical development and scope of clinical trials, plans for initiating future clinical trials, reporting of clinical data for Syndax's product candidates, the association of data with treatment outcomes. 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 Securities and Exchange Commission, including the "Risk Factors" sections contained in its annual report of Form 10-K for the year ended December 31, 2020 and its quarterly report on Form 10-Q for the quarter ended June 30, 2021. 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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3. Kantar 2020 GVHD Expert Interviews N=32 interviews.
4. SMARTImmunology Insights. "Idiopathic Pulmonary Fibrosis." Presentation,March 2020.

SOURCE Syndax Pharmaceuticals, Inc.; Incyte