



Syndax Announces Topline Results from MAXPIRe Phase 2 Trial of Axatilimab in Idiopathic Pulmonary Fibrosis

October 12, 2026

– Trial did not meet the primary endpoint of annualized rate of FVC decline –

– Axatilimab was well tolerated with a safety profile comparable to placebo; no new safety signals were observed –

– Axatilimab continues to advance in multiple trials in cGVHD with results expected later this year and early 2028 –

NEW YORK, Oct. 12, 2026 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals (Nasdaq: SNDX) today announced that the MAXPIRe Phase 2 trial of axatilimab in idiopathic pulmonary fibrosis (IPF) did not meet its primary endpoint of the annualized rate of decline in forced vital capacity (FVC). The safety and tolerability profile observed in MAXPIRe was consistent with previous clinical studies of axatilimab, with no new safety signals identified. Based on the results observed, Syndax does not plan to move forward with further development of axatilimab in IPF. The results from the MAXPIRe trial do not affect ongoing trials of axatilimab in other potential indications.

"The MAXPIRe trial did not meet its primary endpoint, and we are disappointed by this outcome given the promising scientific rationale in IPF," said Nick Botwood, MBBS, Head of Research & Development and Chief Medical Officer at Syndax. "We sincerely thank the patients, caregivers, clinicians and study teams who participated. Axatilimab was well tolerated, with a safety profile consistent with prior studies supporting its continued development and use in cGVHD. There are multiple trials underway in cGVHD where axatilimab has shown remarkable results and we look forward to readouts from these trials later this year and in early 2028."

"We remain highly focused on further advancing revumenib and axatilimab to frontline in the ongoing clinical trials which will unlock significant value for patients and shareholders. And we are well positioned to deliver breakthroughs for patients and build long-term value, with a robust pipeline, multiple upcoming catalysts, and strong financial position," added Michael A. Metzger, Chief Executive Officer of Syndax. "We look forward to working with our partner Incyte as we continue to build Niktimvo into a blockbuster franchise in cGVHD."

MAXPIRe was a 26-week, randomized, double-blind, placebo-controlled, multicenter, Phase 2, 145-patient trial which evaluated the efficacy and safety of axatilimab in patients with IPF who were enrolled across 62 sites in 14 countries. Patients were randomized 2:1 to axatilimab 0.3 mg/kg or placebo every two weeks, with randomization stratified according to the use of background antifibrotic therapy. The primary endpoint of the trial was the annualized rate of decline in FVC. The annualized (52-week) rate was derived using FVC measurements collected over a 26-week period.

Axatilimab was well tolerated in patients with IPF with a safety and tolerability profile comparable to placebo and no new safety signals observed. Rates of treatment-emergent adverse events (TEAEs) leading to treatment discontinuation were low in both arms. The most frequent TEAEs in the axatilimab arm were generally consistent with previous studies. There were no treatment-related fatal adverse events in either arm.

Axatilimab is a first-in-class, CSF-1R-blocking monoclonal antibody that is FDA approved for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg. Axatilimab is being studied in combination with standard-of-care therapies in patients with newly diagnosed cGVHD in two ongoing clinical trials.

About the MAXPIRe Trial

The MAXPIRe trial (NCT06132256) was a Phase 2, 26-week, randomized, double-blind, placebo-controlled, multicenter, 145-patient trial which evaluated the efficacy and safety of axatilimab in patients with IPF who were enrolled across 62 sites in 14 countries. Patients were randomized 2:1 to receive axatilimab 0.3 mg/kg or placebo every two weeks, with randomization stratified according to the use of background antifibrotic therapy.

The primary endpoint of the trial was the annualized rate of decline in forced vital capacity (FVC). The annualized (52-week) rate was derived using FVC measurements collected over a 26-week period and a linear mixed effects model. Secondary endpoints included the time to disease progression, annualized rate of decline in percent predicted FVC from baseline, quality-of-life measures, and change in percent predicted diffusion capacity for carbon monoxide from baseline.

About Niktimvo™ (axatilimab-csfr)

Niktimvo (axatilimab-csfr) is a first-in-class colony stimulating factor-1 receptor (CSF-1R)-blocking antibody approved for use in the U.S. for the treatment of chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg (88.2 lbs).

In 2016, Syndax licensed exclusive worldwide rights to develop and commercialize axatilimab from UCB. In September 2021, Syndax and Incyte entered into an exclusive worldwide co-development and co-commercialization license agreement for axatilimab in chronic GVHD and any future indications.

Axatilimab is being studied in frontline combination trials in chronic GVHD, including a Phase 2 combination trial with ruxolitinib (NCT06388564) and a Phase 3 combination trial with steroids (NCT06585774).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Niktimvo™ (axatilimab-csfr) can cause infusion-related reactions. Infusion-related reactions, including hypersensitivity reactions, occurred in 18% of patients who received Niktimvo in the clinical trial (AGAVE-201), with Grade 3 or 4 reactions in 1.3%.

Premedicate with an antihistamine and an antipyretic for patients who have previously experienced an infusion-related reaction to Niktimvo. Monitor patients for signs and symptoms of infusion-related reactions, including fever, chills, rash, flushing, dyspnea, and hypertension. Interrupt or slow the

rate of infusion or permanently discontinue Niktimvo based on severity of the reaction.

Embryo-Fetal Toxicity

Based on its mechanism of action, Niktimvo may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with Niktimvo and for 30 days after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 44% of patients who received Niktimvo (N=79). Serious adverse reactions in >2 patients included infection (pathogen unspecified) (14%), viral infection (14%) and respiratory failure (5.1%). Permanent discontinuation of Niktimvo due to an adverse reaction occurred in 10% of patients and dose reduction due to adverse reaction occurred in 8% of patients. Dose interruptions due to an adverse reaction occurred in 44% of patients. The adverse reactions leading to dose interruption in >2 patients were viral infection, infection (pathogen unspecified), bacterial infection, musculoskeletal pain, and pyrexia.

The most common (≥15%) adverse reactions, including laboratory abnormalities, were increased aspartate aminotransferase (AST), infection (pathogen unspecified), increased alanine aminotransferase (ALT), decreased phosphate, decreased hemoglobin, viral infection, increased gamma glutamyl transferase (GGT), musculoskeletal pain, increased lipase, fatigue, increased amylase, increased calcium, increased creatine phosphokinase (CPK), increased alkaline phosphatase (ALP), nausea, headache, diarrhea, cough, bacterial infection, pyrexia, and dyspnea.

Clinically relevant adverse reactions in <10% of patients who received Niktimvo included:

- *Eye disorders:* periorbital edema
- *Skin and subcutaneous skin disorders:* pruritus
- *Vascular disorders:* hypertension

Immunogenicity: Anti-Drug Antibody–Associated Adverse Reactions

Across treatment arms in patients with cGVHD who received Niktimvo in clinical trials, among the patients who developed anti-drug antibodies (ADAs), hypersensitivity reactions occurred in 26% (13/50) of patients with neutralizing antibodies (NAb) and in 4% (2/45) of those without NAb.

USE IN SPECIFIC POPULATIONS

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 30 days after the last dose of Niktimvo.

Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating Niktimvo.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with Niktimvo and for 30 days after the last dose of Niktimvo.

DOSAGE AND ADMINISTRATION

Dosage Modifications for Adverse Reactions

Monitor aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), creatine phosphokinase (CPK), amylase, and lipase prior to the start of Niktimvo therapy, every 2 weeks for the first month, and every 1 to 2 months thereafter until abnormalities are resolved. See Table 1 in the Prescribing Information for more recommendations.

Please see the [full Prescribing Information for Niktimvo](#).

About Syndax

Syndax Pharmaceuticals is a commercial-stage biopharmaceutical company advancing innovative cancer therapies. Highlights of the Company's pipeline include Revuforj® (revumenib), an FDA-approved menin inhibitor, and Niktimvo™ (axatilimab-csfr), an FDA-approved monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor. Fueled by our commitment to reimagining cancer care, Syndax is working to unlock the full potential of its pipeline and is conducting several clinical trials across the continuum of treatment. For more information, please visit www.syndax.com/ or follow the Company on [X](#) 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 "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative or plural of those terms, 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 acceptance of Syndax and its partners' products in the marketplace, sales, marketing, manufacturing and distribution requirements, and the potential use of its 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 to Revuforj's or Niktimvo's commercial availability; 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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