



Syndax Pharmaceuticals and Royalty Pharma Enter into \$350 Million Royalty Funding Agreement for Niktimvo™

November 4, 2024

Proceeds expected to support the upcoming planned launches and fund the continued development of Niktimvo and revumenib

Expected to fund Company through profitability; proforma cash approaching \$800 million as of June 30

WALTHAM, Mass. and NEW YORK, Nov. 4, 2024 /PRNewswire/ -- Syndax Pharmaceuticals (Nasdaq: SNDX) and Royalty Pharma plc (Nasdaq: RPRX) today announced that Syndax has entered into a \$350 million synthetic royalty funding agreement with Royalty Pharma based on U.S. net sales of Niktimvo™ (axatilimab-csfr).

"We expect this transaction to fund us through profitability, while ensuring that we continue to participate in the profits from Niktimvo and retain the upside of its future growth. With this significant infusion of capital, we are well positioned to successfully launch two first-in-class medicines and expand their opportunity with additional indications," said Michael A. Metzger, Chief Executive Officer of Syndax. "Royalty Pharma shares our belief that Niktimvo can create significant value as a new treatment option for patients with chronic graft-versus-host disease (GVHD) and recognizes its multi-billion-dollar franchise potential."

"We are excited to partner with Syndax, an innovative oncology company with an exciting pipeline" said Pablo Legorreta, founder and CEO of Royalty Pharma. "Niktimvo is a first-in-class product that has the potential to address the serious and devastating complications associated with chronic GVHD, where there is clear unmet need for additional treatment options. We look forward to Syndax and their partner Incyte launching Niktimvo soon and bringing this important medicine to GVHD patients."

Under the terms of the agreement, Syndax received an upfront payment of \$350 million in exchange for a 13.8% royalty on U.S. net sales of Niktimvo. Royalty payments to Royalty Pharma will cease upon reaching a multiple of 2.35x.

Goldman Sachs & Co. LLC acted as exclusive financial advisor and Cooley LLP acted as legal advisors to Syndax on the transaction. Gibson, Dunn & Crutcher LLP and Dechert LLP acted as legal advisors to Royalty Pharma.

About Niktimvo™ (axatilimab-csfr)

Niktimvo (axatilimab-csfr) is a first-in-class anti-CSF-1R 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 the U.S., Niktimvo will be co-commercialized by Syndax and Incyte. Incyte has exclusive commercialization rights for Niktimvo outside of the U.S. Syndax anticipates that Niktimvo will be launched in the U.S. no later than early first quarter 2025.

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 – a Phase 2 combination trial with ruxolitinib (NCT06388564) is underway and a Phase 3 combination trial with steroids is in preparation. Axatilimab is also being studied in an ongoing Phase 2 trial in patients with idiopathic pulmonary fibrosis (NCT06132256).

Niktimvo is a trademark of Incyte.

All other trademarks are the property of their respective owners.

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 developing an innovative pipeline of cancer therapies. Highlights of the Company's pipeline include revumenib, a selective 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 \(formerly Twitter\)](#) and [LinkedIn](#).

About Royalty Pharma plc

Founded in 1996, Royalty Pharma is the largest buyer of biopharmaceutical royalties and a leading funder of innovation across the biopharmaceutical industry, collaborating with innovators from academic institutions, research hospitals and non-profits through small and mid-cap biotechnology companies to leading global pharmaceutical companies. Royalty Pharma has assembled a portfolio of royalties which entitles it to payments based directly on the top-line sales of many of the industry's leading therapies. Royalty Pharma funds innovation in the biopharmaceutical industry both directly and indirectly - directly when it partners with companies to co-fund late-stage clinical trials and new product launches in exchange for future royalties, and indirectly when it acquires existing royalties from the original innovators. Royalty Pharma's current portfolio includes royalties on more than 35 commercial products, including Vertex's Trikafta, GSK's Trelegy, Roche's Evrysdi, Johnson & Johnson's Tremfya, Biogen's Tysabri and Spinraza, AbbVie and Johnson & Johnson's Imbruvica, Astellas and Pfizer's Xtandi, Novartis' Promacta, Pfizer's Nurtec ODT and Gilead's Trilademy, and 16 development-stage product candidates.

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 about the expected use of the upfront payment, including funding of the Company through profitability; the Company's positioning to launch its products and expand opportunity; expectations of Niktimvo's billion-dollar franchise potential by creating significant value as a new treatment option for patients with chronic GVHD; timing for commercialization of Niktimvo in the U.S.; and the progress, timing, clinical development and scope of clinical trials. 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.

Royalty Pharma Forward-Looking Statements

The information set forth herein does not purport to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this document unless stated otherwise, and neither the delivery of this document at any time, nor any sale of securities, shall under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof.

This document contains statements that constitute "forward-looking statements" as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express the company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of Royalty Pharma's strategies, financing plans, growth opportunities and market growth. In some cases, you can identify such forward-looking statements by

terminology such as "anticipate," "intend," "believe," "estimate," "plan," "seek," "project," "expect," "may," "will," "would," "could" or "should," the negative of these terms or similar expressions. Forward-looking statements are based on management's current beliefs and assumptions and on information currently available to the company. However, these forward-looking statements are not a guarantee of Royalty Pharma's performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances, and other factors. Such risks and uncertainties may cause the statements to be inaccurate and readers are cautioned not to place undue reliance on such statements. Many of these risks are outside of the company's control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this document are made only as of the date hereof. The company does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law.

Certain information contained in this document relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the company's own internal estimates and research. While the company believes these third-party sources to be reliable as of the date of this document, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this document involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while the company believes its own internal research is reliable, such research has not been verified by any independent source.

For further information, please reference Royalty Pharma's reports and documents filed with the U.S. Securities and Exchange Commission ("SEC") by visiting EDGAR on the SEC's website at www.sec.gov.

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