

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): January 25, 2021**

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**AURINIA PHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

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**Canada**

(State or Other Jurisdiction of Incorporation)

**001-36421**

(Commission File No.)

**46-4129078**

(IRS Employer Identification No.)

**#1203-4464 Markham Street  
Victoria, British Columbia  
V8Z 7X8  
(250) 708-4272**

(Address and telephone number of registrant's principal executive offices)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Shares, without par value	AUPH	The Nasdaq Stock Market LLC
Common Shares, without par value	AUP	Toronto Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 7.01 Other Events**

On January 22, 2021, Aurinia Pharmaceuticals Inc. announced that the U.S. Food and Drug Administration had approved LUPKYNIS (voclosporin) in combination with a background immunosuppressive therapy regimen to treat patients with active lupus nephritis. A copy of the associated press release and investor presentation are attached as exhibits to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, are being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

The information contained in the press release and investor presentation is summary information that is intended to be considered in the context of our Securities and Exchange Commission filings and other public announcements that we may make, by press release or otherwise, from time to time. We undertake no duty or obligation to publicly update or revise such information, except as required by law.

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**Item 9.01 Financial Statements and Exhibits**

**(d) Exhibits.**

Exhibit No.	Title
<a href="#">99.1</a>	<a href="#">Press release, dated January 22, 2021, related to receipt of FDA approval for LUPKYNIS</a>
<a href="#">99.2</a>	<a href="#">Aurinia's Investor Presentation, dated January 25, 2021</a>
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the Inline XBRL document)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 25, 2021

**AURINIA PHARMACEUTICALS INC.**

By: */s/ Stephen P. Robertson*

Name: Stephen P. Robertson

Title: EVP, General Counsel, Corporate Secretary and Chief Compliance Officer



## **NEWS RELEASE**

### **FDA Approves Aurinia Pharmaceuticals' LUPKYNIS™ (voclosporin) for Adult Patients with Active Lupus Nephritis**

- *LUPKYNIS is the first FDA-approved oral therapy for lupus nephritis (LN), a condition that causes irreversible kidney damage and increases the risk of kidney failure, cardiac events, and death -*
- *LUPKYNIS demonstrated significantly improved renal response rates compared to typical standard-of-care (SoC) in clinical trials*
- *LUPKYNIS is now commercially available in the U.S. -*
- *Multimedia components are available with this press release ([link here](#)) -*
- *Conference call to be hosted Monday, January 25, 2021, 8:30 a.m. ET -*

**VICTORIA, British Columbia and ROCKVILLE, Maryland – January 22, 2021** - Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX: AUP) ("Aurinia" or the "Company") today announced that the U.S. Food and Drug Administration (FDA) has approved LUPKYNIS™ (voclosporin) in combination with a background immunosuppressive therapy regimen to treat adult patients with active lupus nephritis (LN). LUPKYNIS is the first FDA-approved oral therapy for LN. LN causes irreversible kidney damage and significantly increases the risk of kidney failure, cardiac events, and death. It is one of the most serious and common complications of the autoimmune disease systemic lupus erythematosus (SLE). LUPKYNIS is now available to patients in the United States (U.S.).

In pivotal trials, patients treated with LUPKYNIS in combination with standard-of-care (SoC) were more than twice as likely to achieve renal response and experienced a decline in urine protein creatinine ratio (UPCR) twice as fast as patients on typical SoC alone. UPCR is a standard measurement used to monitor protein levels in the kidney. Early intervention and kidney response are linked to better long-term outcomes and prevent irreversible kidney damage. Patients treated with LUPKYNIS showed improved response rates in all parameters across immunologically-active classes of LN studied.

"The LUPKYNIS approval marks a turning point for the lupus nephritis community – patients, caregivers, families, and healthcare professionals – all of whom we thank for their partnership in the development of this innovative novel treatment. We are thrilled to bring LUPKYNIS to the people impacted by this devastating condition," said Peter Greenleaf, President and Chief Executive Officer of Aurinia Pharmaceuticals. "The approved label supports the efficacy and safety of LUPKYNIS as well as Aurinia's proprietary and patented eGFR pharmacodynamic dosing protocol. We have worked tirelessly to put the correct team and infrastructure in place to ensure we are ready for swift commercial adoption of LUPKYNIS."

"For years treating patients with lupus nephritis has been challenging. We have had a very limited number of therapeutic options, and these have been only modestly effective but highly toxic," said Brad H. Rovin, M.D., Professor of Medicine and the Director of the Division of Nephrology, Ohio State University Wexler Medical Center, and AURORA clinical trial investigator. "The FDA approval of

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LUPKYNIS allows us to treat patients safely and more effectively with a rapid acting therapy which requires far less steroids, something our patients will appreciate.”

To assist LUPKYNIS patients and the healthcare provider (HCPs) who prescribe the treatment, Aurinia has developed and launched Aurinia Alliance™, a patient support program featuring dedicated nurse case managers who provide personalized educational resources and assistance in navigating insurance and Aurinia medication costs throughout each patient’s LUPKYNIS treatment journey. To learn more about Aurinia Alliance or LUPKYNIS, visit [www.LUPKYNIS.com](http://www.LUPKYNIS.com).

“People with lupus nephritis have desperately needed approved treatments to help them avoid irreversible kidney damage and the eventual need for kidney transplant,” said Stevan W. Gibson, President and CEO, Lupus Foundation of America. “The approval of a tailored therapy represents a significant step forward in treating lupus nephritis and is excellent news for the lupus community.”

“Despite strong efforts in research to find solutions for SLE and LN, options to-date have been limited. Once patients progress to LN, they face inevitable life-altering effects,” said Kenneth M. Farber, President and CEO, Lupus Research Alliance. “We have long supported Aurinia Pharmaceuticals and are encouraged by the U.S. FDA approval of voclosporin, a much-needed oral treatment option to address the challenges faced by people living with LN.”

“New treatments indicated specifically for lupus nephritis will contribute to our quest for health equity in kidney diseases,” commented National Kidney Foundation’s Chief Medical Officer Joseph Vassalotti, M.D. “Interventions that are effective to manage and potentially prevent irreversible kidney damage are exciting for people living with lupus nephritis and their clinicians in nephrology and rheumatology.”

“As a patient-led organization who understands all too well the urgent need for more efficacious treatments for people struggling to live with diseases of unmet need like lupus nephritis, we are thrilled with the approval of LUPKYNIS,” said Kathleen A. Arntsen President and CEO of Lupus and Allied Diseases Association. “There is now a new treatment for this debilitating and life-diminishing condition that is four times higher for people of African descent and Asians and two times higher for Hispanics/Latinos and Native Americans. At a time when our nation faces extreme challenges such as addressing and overcoming social inequities and health disparities, this is welcome and promising news, especially since both lupus nephritis and COVID-19 disproportionately impact communities of color.”

LUPKYNIS was approved by the FDA under Priority Review and was previously granted Fast Track designation from the Agency in 2016. To learn more visit [www.auriniapharma.com](http://www.auriniapharma.com).

#### Multimedia Components and Conference Call Information

Multimedia components are available with this press release ([link here](#)). Aurinia will host a conference call and webcast to discuss the approval of LUPKYNIS on Monday, January 25, 2021 at 8:30 a.m. ET. The webcast can be accessed on the investor section of the Aurinia website at [www.auriniapharma.com](http://www.auriniapharma.com). To participate in the teleconference, please dial +1-877-407-9170 (Toll-free U.S. & Canada).

#### Clinical Trial Overview of LUPKYNIS (voclosporin)

The approval of LUPKYNIS is based on data from Aurinia’s pioneering late-stage global clinical studies in LN – the pivotal AURORA Phase 3 study and the AURA-LV Phase 2 study. These studies together demonstrated the ability of LUPKYNIS treatment to significantly improve outcomes as reported up to 52

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weeks, for patients on several parameters when added to the typical SoC, mycophenolate mofetil (MMF), and low dose steroids.

In both studies, a total of 533 patients with LN were randomized to receive either LUPKYNIS 23.7 mg or placebo twice daily used with SoC. All patients were dosed with concurrent MMF at a target dose 2 g/day. In both studies, initial treatment with intravenous (IV) methylprednisolone up to a cumulative dose of 1 g was administered on Days 1 and 2, and all patients received a subsequent taper of oral corticosteroids. The starting dose of oral prednisone was 20 mg/day for patients with a body weight of <45 kg and 25 mg/day for patients  $\geq$ 45 kg. The dose of oral corticosteroid was tapered down to achieve a target dose of 2.5 mg/day by Week 16. The studies enrolled patients with LN of Class III or IV (alone or in combination with Class V) or pure Class V. Enrolled patients were required to have baseline eGFR >45 mL/min/1.73 m<sup>2</sup>.

In the Phase 3 study, at one year, LUPKYNIS plus SoC was more than two times as effective at achieving a complete renal response than the SoC alone. Patients in the study taking LUPKYNIS also achieved a 50 percent reduction in UPCR twice as fast as SoC, and a higher portion of LUPKYNIS-treated patients achieved a complete renal response at 24 weeks compared to patients receiving SoC. The study results were achieved using a protocol-defined steroid taper. Patients treated with LUPKYNIS showed improved response rates in all parameters across immunologically-active classes of LN studied.

The most common adverse reactions ( $\geq$ 3%) were glomerular filtration rate decreased, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.

#### About Lupus Nephritis

Lupus nephritis (LN) is a serious progression of SLE, a chronic, complex and autoimmune disease. About 200,000-300,000 people live with SLE in the U.S. and approximately one out of three of these individuals have already developed LN at the time of SLE diagnosis. If poorly controlled, LN can lead to permanent and irreversible tissue damage within the kidney, resulting in kidney failure. Black and Asian individuals with SLE are four times more likely to develop LN and individuals with Hispanic ancestry are approximately twice as likely to develop the disease when compared with Caucasian individuals. Black and Hispanic individuals with SLE also tend to develop LN earlier and have poorer outcomes when compared to Caucasian individuals.

#### About Aurinia

Aurinia Pharmaceuticals is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations that are impacted by serious diseases with a high unmet medical need. The Company has introduced LUPKYNIS (voclosporin), the first FDA-approved oral therapy dedicated for the treatment of adult patients with active lupus nephritis (LN). The Company's head office is in Victoria, British Columbia, its U.S. commercial hub is in Rockville, Maryland, and the Company focuses its development efforts globally.

### INDICATION AND IMPORTANT SAFETY INFORMATION

#### INDICATIONS

LUPKYNIS is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN). *Limitations of Use:* Safety and efficacy of LUPKYNIS have not been established in combination with cyclophosphamide. Use of LUPKYNIS is not recommended in this situation.

recommended in this situation.

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## IMPORTANT SAFETY INFORMATION

### BOXED WARNINGS: MALIGNANCIES AND SERIOUS INFECTIONS

Increased risk for developing malignancies and serious infections with LUPKYNIS or other immunosuppressants that may lead to hospitalization or death.

**CONTRAINDICATIONS:** LUPKYNIS is contraindicated in patients taking strong CYP3A4 inhibitors because of the increased risk of acute and/or chronic nephrotoxicity, and in patients who have had a serious/severe hypersensitivity reaction to LUPKYNIS or its excipients.

### WARNINGS AND PRECAUTIONS

**Lymphoma and Other Malignancies:** Immunosuppressants, including LUPKYNIS, increase the risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to increasing doses and duration of immunosuppression rather than to the use of any specific agent.

**Serious Infections:** Immunosuppressants, including LUPKYNIS, increase the risk of developing bacterial, viral, fungal, and protozoal infections (including opportunistic infections), which may lead to serious, including fatal, outcomes.

**Nephrotoxicity:** LUPKYNIS, like other calcineurin inhibitors (CNIs), may cause acute and/or chronic nephrotoxicity. The risk is increased when CNIs are concomitantly administered with drugs associated with nephrotoxicity.

**Hypertension:** Hypertension is a common adverse reaction of LUPKYNIS therapy and may require antihypertensive therapy.

**Neurotoxicity:** LUPKYNIS, like other CNIs, may cause a spectrum of neurotoxicities: severe include posterior reversible encephalopathy syndrome (PRES), delirium, seizure, and coma; others include tremor, paresthesia, headache, and changes in mental status and/or motor and sensory functions.

**Hyperkalemia:** Hyperkalemia, which may be serious and require treatment, has been reported with CNIs, including LUPKYNIS. Concomitant use of agents associated with hyperkalemia may increase the risk for hyperkalemia.

**QTc Prolongation:** LUPKYNIS prolongs the QTc interval in a dose-dependent manner when dosed higher than the recommended lupus nephritis therapeutic dose. The use of LUPKYNIS in combination with other drugs that are known to prolong QTc may result in clinically significant QT prolongation.

**Immunizations:** Avoid the use of live attenuated vaccines during treatment with LUPKYNIS.

Inactivated vaccines noted to be safe for administration may not be sufficiently immunogenic during treatment with LUPKYNIS.

**Pure Red Cell Aplasia:** Cases of pure red cell aplasia (PRCA) have been reported in patients treated with another CNI immunosuppressant. If PRCA is diagnosed, consider discontinuation of LUPKYNIS.

**Drug-Drug Interactions:** Avoid co-administration of LUPKYNIS and strong CYP3A4 inhibitors or with strong or moderate CYP3A4 inducers. Reduce LUPKYNIS dosage when co-administered with moderate CYP3A4 inhibitors. Reduce dosage of certain P-gp substrates with narrow therapeutic windows when co-administered.

### ADVERSE REACTIONS

The most common adverse reactions ( $\geq 3\%$ ) were glomerular filtration rate decreased, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.

### SPECIFIC POPULATIONS

**Pregnancy/Lactation:** May cause fetal harm. Advise not to breastfeed.

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**Renal Impairment:** Not recommended in patients with baseline eGFR  $\leq 45$  mL/min/1.73 m<sup>2</sup> unless benefit exceeds risk. Severe renal impairment: Reduce LUPKYNIS dose.

**Mild and Moderate Hepatic Impairment:** Reduce LUPKYNIS dose. Severe hepatic impairment: Avoid LUPKYNIS use.

Please see **Prescribing Information, including Boxed Warning, and Medication Guide** for LUPKYNIS.

### **Forward-Looking Statements**

Certain statements made in this press release may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include but are not limited to statements or information with respect to: Aurinia's estimates as to the number of patients with SLE in the U.S. and the proportion of those persons who will develop LN; the proportion of Black and Asian individuals, and individuals with Hispanic ancestry, compared to Caucasian individuals, to develop LN; Aurinia enhancing access with a variety of patient services and healthcare engagement initiatives. It is possible that such results or conclusions may change based on further analyses of these data. Words such as "anticipate", "will", "believe", "estimate", "expect", "intend", "target", "plan", "goals", "objectives", "may" and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: the accuracy of the results from our clinical trials; the accuracy of reported data from third party studies and reports; that Aurinia's intellectual property rights are valid and do not infringe the intellectual property rights of third parties. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

Forward-looking information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following difficulties we may experience in completing the commercialization of voclosporin; the market for the LN business may not be as estimated; Aurinia may have to pay unanticipated expenses; Aurinia may not be able to obtain sufficient supply to meet commercial demand for voclosporin in a timely fashion; unknown impact and difficulties imposed by the COVID-19 pandemic on our business operations including nonclinical, clinical, regulatory and commercial activities; the results from our clinical studies and from third party studies and reports may not be accurate; and our assets or business activities may be subject to disputes that may result in litigation or other legal claims. Although we have attempted to identify factors that would cause actual actions, events or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond our control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information.

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All forward-looking information contained in this presentation is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business, can be found in Aurinia's most recent Annual Information Form available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at [www.sedar.com](http://www.sedar.com) or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at [www.sec.gov/edgar](http://www.sec.gov/edgar)

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# Changing the Course of Autoimmune Disease

LUPKYNIS™ FDA Approval and Launch

January 25, 2021



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## Cautionary Statement regarding Forward-Looking Information

Certain statements made in this slide presentation may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include but are not limited to statements or information with respect to: the approved label providing patent protection to December 2037; the estimated patient population for LN; potential peak annual US net sales of greater than \$1 billion; LUPKYNIS being positioned for first line treatment; the results of our clinical trials; our commercialization strategy; timing of product availability; and our expected average annualized net revenue of ~\$65,000. It is possible that such results or conclusions may change based on further analyses of these data. Words such as "anticipate," "will," "believe," "estimate," "expect," "intend," "target," "plan," "goals," "objectives," "may" and other similar words and expressions, identify forward-looking statements.

We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about the patient population for LN; the adherence to treatment of LN patients; the average dosing per patient; the average annualized net revenue per patient; that another company will not create a substantial competitive product for Aurinia's LN business without violating Aurinia's intellectual property rights; Aurinia being able to extend and protect its patents for LN on terms acceptable to Aurinia; the size of the LN market; the accuracy of results from our clinical trials; the accuracy of reported data from third party studies and reports; and that Aurinia's intellectual property rights are valid and do not infringe the intellectual property rights of other parties; that our suppliers and contractors will meet their contracted requirements. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

Forward-looking information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following: difficulties we may experience in completing the commercialization of LUPKYNIS; the market and patient population for the LN business may not be as estimated; Aurinia may have to pay unanticipated expenses; Aurinia not being able to extend or fully protect its patent portfolio for LUPKYNIS; competitors may arise with similar products; Aurinia may not be able to obtain sufficient supply to meet commercial demand for LUPKYNIS in a timely fashion; unknown impact and difficulties imposed by the COVID-19 pandemic on our business operations including nonclinical, clinical, regulatory and commercial activities; the results from our clinical studies and from third party studies and reports may not be accurate; and our assets or business activities may be subject to disputes that may result in litigation or other legal claims. Although we have attempted to identify factors that would cause actual actions, events or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond our control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information. Except as required by law, Aurinia will not update forward-looking information.

All forward-looking information contained in this presentation is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business, can be found in Aurinia's most recent Annual Information Form available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at [www.sedar.com](http://www.sedar.com) or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at [www.sec.gov/edgar](http://www.sec.gov/edgar)

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# Agenda

- 1 Introduction

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- 2 Lupus nephritis (LN) and LUPKYNIS™ Clinical Review

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- 3 Launch Ready: Commercial Strategy

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- 4 Q&A

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# LUPKYNIS™ Now FDA-Approved for Active Lupus Nephritis



## Indication

- LUPKYNIS is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN)

## Dosing

- Three capsules (23.7mg) twice daily, no-serum drug monitoring required
- Dose modifications based on Aurinia's proprietary personalized pharmacodynamic dosing protocol - (eGFR based dosing modifications)

## Safety

- Boxed Warning, warnings and precautions consistent with other CNI-immunosuppressive treatments
- Most common AEs ( $\geq 3\%$ ) were glomerular filtration rate decreased, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.

eGFR=estimated glomerular filtration rate; AEs=Adverse events



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# LUPKYNIS: Added Long-Term Value in Favorable Product Label

UNITED STATES  
PATENT AND TRADEMARK OFFICE



## Patent portfolio includes

- Novel voclosporin composition of matter (US 7,332,472)
- Dosing protocol based on personalized pharmacodynamic eGFR parameters (US 10,286,036)

## January 2021

- U.S. FDA approved LUPKYNIS
- Personalized eGFR dosing detailed in PI Dosage & Administration Section 2.3

Approved label provides additional anticipated patent life:

Late 2027  
(Composition of matter patent, Hatch-Waxman, pediatric ext.)

December 2037  
(Personalized pharmacodynamic e-GFR dosing protocol)



1. Patent expiry reflects Orange Book inclusion of '036 patent.

eGFR=estimated glomerular filtration rate; PI=package insert

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## LUPKYNIS is Positioned for First-Line Treatment in Active LN



### **Superior renal response rates vs SoC alone:**

In clinical trials, patients treated with LUPKYNIS + standard-of-care (SoC) were more than twice as likely to achieve a complete renal response compared to typical SoC alone



### **Proteinuria reductions twice as fast as SoC:**

Patients treated with LUPKYNIS + SoC achieved target UPCR of  $\leq 0.5$  mg/mg in half the median time compared to typical SoC alone



### **Demonstrated efficacy with reduced steroid use:**

80% of patients in the pivotal trial reduced steroid use to  $\leq 2.5$  mg/day at Week 16 and 75% were on this dose at Week 52



### **Showed improved response rates in all parameters across immunologically-active classes of LN studied**

Evaluated across a diverse patient population



**Novel orally administered therapy, with no therapeutic drug-level monitoring (TDM) required**

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# Lupus Nephritis (LN) and LUPKYNIS Clinical Review



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## LN: A Serious Rare Disease that Disproportionately Affects Women and Minority Populations








- Systemic lupus erythematosus (SLE) affects 200 - 300K patients in the US
  - Approximately 1 of 3 patients have already developed LN at the time of SLE diagnosis
- Patients with LN are more likely to be female (90% of patients with SLE)
- Non-white SLE patients (Blacks, Asians, and those of Hispanic ethnicity) are more likely to develop LN than whites





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# LN is associated with significantly elevated risk of kidney failure, cardiac events, and death

Clinical Burden <i>Compared to Non-renal SLE</i>		Economic Burden <i>Compared to Non-renal SLE</i>
 <p><b>LN accelerates nephron loss</b></p>	 <p><b>~45x</b> higher risk of kidney failure</p> <p><b>~10% to 30%</b> of patients with LN experience kidney failure within 15 years</p>	 <p><b>~2x</b> higher hospitalization rate</p>
	 <p><b>~8x</b> risk of myocardial infarction (MI)</p> <p><b>~5x</b> risk of cardiovascular mortality (CVM)</p>	 <p><b>~2x</b> longer hospital stays</p>
	 <p><b>~3x</b> risk of premature death</p>	 <p><b>~5x</b> greater annual costs if kidney failure develops</p>

CVM (HR=4.9; 95% CI: 1.8-13.7; P=0.002)  
 MI (HR=8.5; 95% CI: 2.2-33; P=0.002)  
 CI=confidence interval; HR=hazard ratio.

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# LN Treatment Guidelines Support Decreased Proteinuria to Reduce Kidney Damage

Target Proteinuria Decrease of:



by 3 months



by 6 months



by 12 months

EULAR/ERA-EDTA guidelines recommend more rigorous targets for treatment goals.  
These guidelines emphasize reducing cumulative glucocorticoid dose to reduce the risk of end-organ damage

ACR 2012 response is determined by physician's own judgement and clinical impression

ACR=American College of Rheumatology; ERA-EDTA=European Renal Association-European Dialysis and Transplant Association; EULAR=European League Against Rheumatism.

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# LUPKYNIS Showed Significantly Higher Rate of Renal Response

In pivotal study, patients treated with LUPKYNIS + SoC were nearly **3x more likely to have a renal response** vs typical SoC alone (OR=2.65)\*

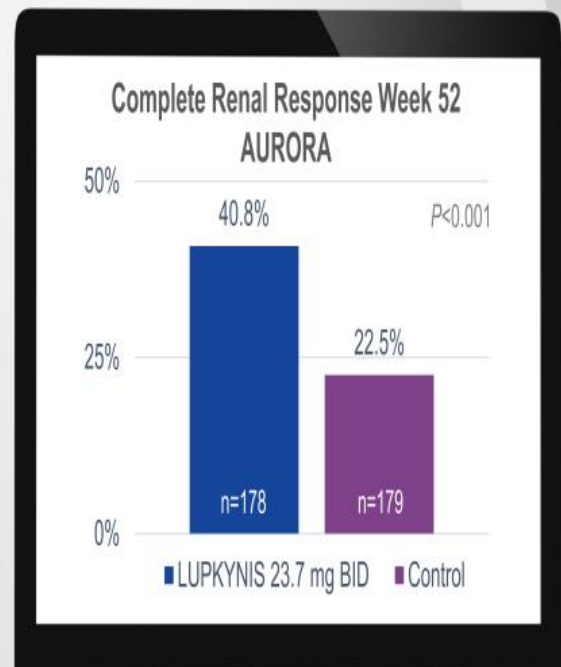
Definition of renal response was based on rigorous criteria:

Confirmed UPCR of  $\leq 0.5$  mg/mg

Stable renal function:  $\geq 60$  mL/min/1.73m<sup>2</sup> or no confirmed decrease from baseline in eGFR of  $\geq 20\%$ )

Presence of sustained, low-dose steroids ( $\leq 10$  mg prednisone from weeks 44 to 52)

No administration of rescue medications

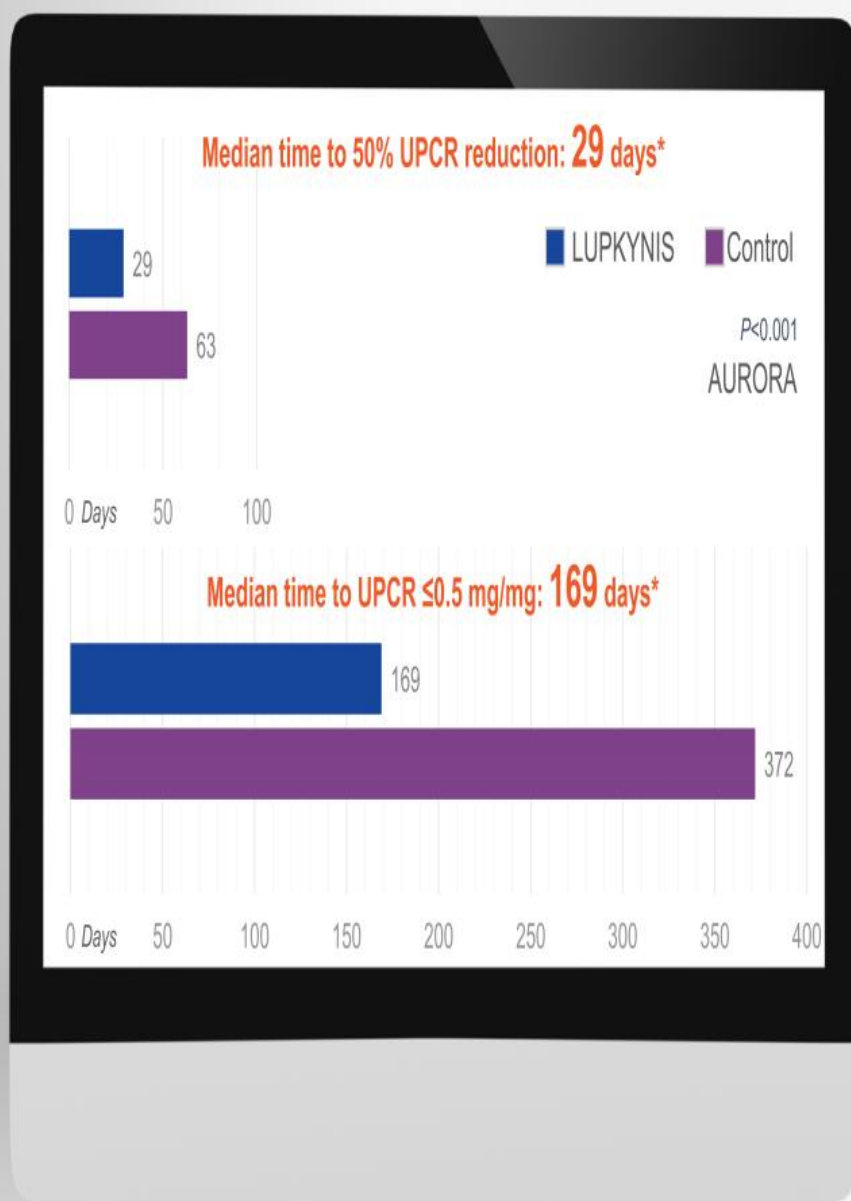


\* AURORA 1 data (not pooled)

BID=twice daily; eGFR=estimated glomerular filtration rate; OR=odds ratio.

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## LUPKYNIS Reduced Proteinuria Twice as Fast as SoC



- Reductions achieved while rapidly reducing steroids to low maintenance doses ( $\leq 2.5$  mg/day)
- Consistent results across immunologically-active classes of LN studied



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## LUPKYNIS Safety Profile

- No unexpected adverse events
- Boxed Warning, warnings and precautions consistent with other CNI-immunosuppressant therapies
- Efficacy and response with no therapeutic drug-level monitoring (TDM) required



Most commonly reported Adverse Reactions  $\geq 3\%$  of patients treated with LUPKYNIS 23.7 mg 2x/day and  $\geq 2\%$  higher than Placebo in AURA-LV and AURORA

Adverse Reaction	LUPKYNIS 23.7 mg twice a day (n=267)	Placebo (n=266)
Glomerular filtration rate decreased	26%	9%
Hypertension	19%	9%
Diarrhea	19%	13%
Headache	15%	8%
Anemia	12%	6%
Cough	11%	2%
Urinary tract infection	10%	6%
Abdominal pain upper	7%	2%
Dyspepsia	6%	3%
Alopecia	6%	3%
Renal impairment	6%	3%
Abdominal pain	5%	2%
Mouth ulceration	4%	1%
Fatigue	4%	1%
Tremor	3%	1%
Acute kidney injury	3%	1%
Decreased appetite	3%	1%

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## Our Commitment to Patients Living with LN

- Approval and label are the result of a pioneering clinical development team
- Clinical development and regulatory teams committed to advancing the standard of care and establishing new frontline therapy for people living with active LN
- LUPKYNIS continues to be evaluated in AURORA-2, blinded 2-year continuation study, and pediatric, adolescent, and PMR/PMCs from FDA

Product & Indication	Development Stage			
	Phase 1	Phase 2	Phase 3	Approval
<p><b>voclosporin</b></p> <p>Active Lupus Nephritis (LN)</p>				

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# Launch Execution: Commercial Strategy



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# Driving LUPKYNIS Adoption – Commercialization Strategy



Establish **LUPKYNIS**  
as Standard of Care



Enable **Optimal**  
**Outcomes for**  
**Patients**



Ensure **no delays in**  
**LN Diagnosis**



Realize LUPKYNIS  
Value Proposition with  
**Unrestricted Access**  
for Appropriate  
**Patients**



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## Robust Infrastructure to Address All Key Stakeholders



### Physicians

- >150 professionals
- Sales force with deep nephrology and rheumatology experience
- Field based access and reimbursement professionals
- Medical and scientific liaisons



### Patients

- Personalized patient support program: *Aurinia Alliance™*
- Dedicated nurse case managers for 1:1 support throughout treatment journey
- Dedicated reimbursement specialists
- Direct to patient digital education



### Payers

- Field based access team with deep pharmacy benefit experience
- Robust financial support programs including co-pay, uninsured, and underinsured patient support



### Advocacy

- HQ and field-based teams
- Actively engaging with local and national lupus, LN, and health disparity professional and patient focused advocacy organizations

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# LUPKYNIS: Compelling Value Proposition



## Addresses Unmet Medical Need

- LN is associated with increased risk of kidney failure, cardiac events, and death
- **Early improvement in proteinuria and renal response is linked to better long-term outcomes and prevents irreversible kidney damage**
- About 50% of LN patients do not achieve a clinically meaningful response at 1 yr.



## Efficacy

- Patients on LUPKYNIS + SoC **were more than twice as likely to achieve complete renal response compared to patients on SoC alone**
- Improved response rates regardless of immunologically-active LN class



## Rapid Response

- Patients on LUPKYNIS + SoC experienced a decline in UPCR **twice as fast as patients on SoC alone.**



## Reduced Steroid Burden

- **75% of patients on a low steroid dose ( $\leq 2.5\text{mg}$ ) at 1 yr.**



## Unique Support

- Personalized patient support through the **Aurinia Alliance**

### LUPKYNIS Value Proposition

**Expected average annualized net revenue per patient: ~\$65K**

Based on patient-specific dosing regimens and accounting for factors including mandatory rebates, channel discounts, and anticipated patient adherence

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# LUPKYNIS Commercial Launch Uniquely Prepared for Success

## 2020 Pre-launch prepared team and market

- Fully staffed **Commercial Team** with extensive Rheumatology and Nephrology experience
- Identified ~12k **physician targets**
- Completed **physician profiling** of highest SLE prescribers
- Delivered **Speaker/Disease Awareness** programs reaching more than 1,000 HCPs
- Launched first Lupus Nephritis pharma-sponsored **consumer disease state awareness (DSA) program** with over 140K impressions
- Engaged HCPs in **Academic Centers** with DSA campaign notwithstanding COVID-related restrictions
- Executed **pre-approval information exchange with more than 50 payers** covering two-thirds of commercially insured lives.

**Approval Date: January 22, 2021**

## 2021 Launch Execution

- Aurinia has more than **\$400M in cash**; well capitalized for successful launch
- **Product available for prescribing**
- Patient Support Program **Aurinia Alliance online** with dedicated nurse case managers and reimbursement support
- **Targeting** Nephrologists & Rheumatologists with active LN patients
- Launching in-person and virtual **branded campaign**
- Ensure **patient education** regionally through advocacy and HCP engagement
- **Potential peak annual U.S. net sales of greater than \$1 billion\***

\* Aurinia Estimate

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Q&A





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# Changing the Course of Autoimmune Disease

**LUPKYNIS™ FDA Approval and Launch**

January 25, 2021



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