

January 22, 2021



# 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 & ROCKVILLE, Md.--(BUSINESS WIRE)-- [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 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 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 ≥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 (≥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.

### **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.

**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.

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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