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Aurinia Announces Licensing Partner Otsuka Filed Initial Marketing Authorization Application (MAA) for Voclosporin with the European Medicines Agency (EMA)

VICTORIA, British Columbia & ROCKVILLE, Md.--(BUSINESS WIRE)-- [Aurinia Pharmaceuticals Inc.](#) (NASDAQ: AUPH / TSX: AUP) (the Company) announced today that the Company's licensing partner, Otsuka Pharmaceutical Europe Ltd. (OPEL), filed an initial Marketing Authorization Application (MAA) for voclosporin for the treatment of lupus nephritis (LN) to the European Medicines Agency (EMA). LN is a complication of the autoimmune disease systemic lupus erythematosus (SLE) that seriously impacts the kidneys. In January 2021, the U.S. Food and Drug Administration (FDA) approved voclosporin in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active LN and it is currently available in the U.S. under the brand name LUPKYNIS™.

In [December 2020](#), Aurinia entered into a collaboration and licensing agreement with OPEL for the development and commercialization of voclosporin for the treatment of LN in the European Union, Japan, the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein, and Ukraine. Once the MAA is approved, OPEL would be authorized to market voclosporin in the European Union, Norway, Iceland, and Liechtenstein. As part of the agreement, Aurinia received a \$50 million U.S. upfront cash payment with the potential to secure up to \$50 million U.S. in additional regulatory and reimbursement milestone payments. In addition, Aurinia will receive tiered royalties ranging from 10 to 20 percent, dependent on net and annual sales following commercialization, along with additional milestone payments based on the attainment of certain annual sales by OPEL. Voclosporin will be provided to OPEL under a cost-plus supply agreement.

"Lupus nephritis is a serious, complex condition that historically has lacked dedicated, approved treatment options," said Peter Greenleaf, President and Chief Executive Officer of Aurinia Pharmaceuticals. "We look forward to continuing to work with Otsuka to expand access to voclosporin and provide patients and physicians access to this new therapy that addresses a significant unmet need in lupus nephritis."

About Lupus Nephritis

LN is a serious manifestation of SLE, a chronic and complex autoimmune disease. Approximately one out of three of these individuals with SLE will develop LN. 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 of 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, Inc. 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'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 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 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 ≤ 45 mL/min/1.73 m² 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 estimated proportion of Black and Asian individuals, and individuals with Hispanic ancestry, compared to Caucasian individuals, to develop LN. 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; and the accuracy of reported data from third party studies and reports. 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; and the results from our clinical studies and from third party studies and reports may not be accurate. 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 report on Form 10-K available by accessing the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at www.sec.gov/edgar or the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at www.sedar.com.

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