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Aurinia Announces Additional Analysis of its AURORA 1 Phase 3 Study Data Presented at ERA-EDTA 2021 Congress

- New examination of AURORA 1 Phase 3 data demonstrates increased renal response rates with LUPKYNIS™ (voclosporin) used in combination with MMF and low-dose steroids in patients with lupus nephritis regardless of target urine protein creatinine ratio (UPCR) -

- The assessment follows the presentation of first interim results of AURORA 2 continuation study at EULAR 2021 -

VICTORIA, British Columbia & ROCKVILLE, Md.--(BUSINESS WIRE)--

Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX: AUP) (Aurinia or the Company) today presented an analysis of its Phase 3 AURORA 1 study data at the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) 2021 Congress. The presentation follows the recent introduction of new data from an interim analysis of the AURORA 2 continuation study at the European Alliance of Associations for Rheumatology (EULAR) 2021 Congress.

In the assessment presented at ERA-EDTA, researchers conducted a sensitivity study evaluating renal response (RR) with additional urine protein creatinine ratio (UPCR) targets given the efficacy demonstrated of voclosporin in terms of proteinuria reduction in the AURORA 1 study. This examination demonstrated that patients treated with voclosporin in addition to mycophenolate mofetil (MMF) and low-dose steroids achieved statistically significant increased renal response rates regardless of the level of UPCR, including at an even more stringent ≤0.3 mg/mg target. The data further support the efficacy and safety observed with voclosporin in the Phase 3 AURORA 1 trial.

“This new look at the data on LUPKYNIS is significant because it demonstrates the ability of the therapy to deliver meaningful renal response rates at UPCR levels beyond the initial target in its Phase 3 study,” said study co-author, Maria Dall’Era, M.D., Director, UCSF Lupus Clinic and Rheumatology Clinical Research Center, Department of Medicine, University of California, San Francisco. “Multiple previous studies have suggested that level of proteinuria represents the best clinical predictor of long-term kidney outcome. Thus, seeing the benefits of LUPKYNIS even in the most stringent UPCR levels is encouraging for lupus nephritis patients and the physicians treating this challenging condition.”

The ERA-EDTA assessment of Aurinia’s Phase 3 AURORA 1 study included a total of 179 participants in the voclosporin (23.7 mg BID) arm and 178 participants in the control arm from the AURORA 1 trial. All participants received MMF (target 1 g BID) and low-dose oral steroids (initiated at 20-25 mg/day and tapered to 2.5 mg/day at 16 weeks). The UPCR component of RR was revised to include UPCR targets at 0.2 mg/mg intervals above and

below the original ≤0.5 target used for the primary endpoint in AURORA 1 (i.e., ≤0.7 mg/mg or ≤0.3 mg/mg, respectively). Complete renal response (CRR) defined as achievement of UPCR ≤0.5 mg/mg with stable renal function (eGFR ≥60 mL/min/1.73 m^2 and no decrease >20% from baseline) in the presence of sustained, low-dose steroids (in the 8 weeks prior to assessment) and no use of rescue medication. Complete renal response analysis at approximately one year included Week 52 data from AURORA 1. Odds ratios for RR at 26 weeks and 52 weeks of treatment were analyzed using a logistic regression model with terms for treatment, baseline UPCR, biopsy class, and MMF use at baseline and region.

Renal Response at One Year

	Control (n=178)	Voclosporin (n=179)	Odds Ratio vs Control
UPCR Threshold	Percent of participants with renal response		
≤0.7 mg/mg	32.0%	46.9%	2.07
≤0.5 mg/mg	22.5%	40.8%	2.65
≤0.3 mg/mg	15.7%	28.5%	2.27

In the AURORA 1 trial, LUPKYNIS was well tolerated with no unexpected safety signals. Serious adverse events (SAEs) were reported in 21% of those treated with LUPKYNIS and in 21% of those in the control group. Infection and infestations were the most commonly reported SAEs, in 10% of the LUPKYNIS group and 11% of the control group. Overall mortality in the AURORA 1 trial was low, with six deaths observed; one in the LUPKYNIS group and five in the control group. Additionally, the LUPKYNIS group showed no notable decrease at Week 52 in mean eGFR or increase in mean blood pressure, lipids or glucose, which are common adverse events associated with traditional calcineurin inhibitors (CNIs).

About Lupus Nephritis

LN is a serious manifestation of systemic lupus erythematosus (SLE), a chronic and complex autoimmune disease. About 200,000-300,000 people live with SLE in the U.S. and approximately one out of three of these individuals 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 LUPKYNIS

LUPKYNIS is the first FDA-approved oral treatment for the treatment of adult patients with active LN. A novel, structurally modified CNI, LUPKYNIS has a dual mechanism of action, acting as an immunosuppressant through inhibition of T-cell activation and cytokine production and promoting podocyte stability in the kidney. The recommended starting dose of LUPKYNIS is three capsules twice daily with no requirement for serum drug monitoring. Dose modifications can be made based on Aurinia's proprietary personalized eGFR based dosing protocol. Boxed Warning, warnings and precautions for LUPKYNIS are consistent

with those of other CNI-immunosuppressive treatments.

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'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 (≥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 m^2 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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