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Aurinia Announces Updated Interim Results from the AURORA 2 Continuation Study of LUPKYNIS (voclosporin) for the Treatment of Lupus Nephritis

- Longest available outcomes data with LUPKYNIS will be presented virtually during American College of Rheumatology (ACR) Convergence 2021; final results expected by the end of 2021 –

- Updated interim analysis shows sustained safety and tolerability of LUPKYNIS compared with placebo -

- Individuals treated with LUPKYNIS sustained meaningful reductions in proteinuria with stable eGFR at 30 months -

VICTORIA, British Columbia--(BUSINESS WIRE)--[Aurinia Pharmaceuticals Inc.](#) (NASDAQ: AUPH) (Aurinia or the Company), a biopharma company committed to delivering therapeutics that change the course of autoimmune disease, today announced updated interim results from the AURORA 2 continuation study evaluating the long-term safety and tolerability of LUPKYNIS™ (voclosporin) for the treatment of lupus nephritis (LN) in patients with systemic lupus erythematosus (SLE), a chronic and complex autoimmune disease. The updated results will be presented virtually on Nov. 8 during [Plenary Session III at 10:45 a.m. EST](#) during The American College of Rheumatology (ACR) Convergence 2021.

In the interim analysis, patients in the voclosporin group maintained meaningful reductions in proteinuria. From pre-treatment baseline in AURORA 1 to month 30 in AURORA 2, mean urine protein/creatinine ratio (UPCR) was -3.32 mg/mg for the voclosporin group (n=90) and -2.55 mg/mg for the control group (n=78). In the voclosporin group, estimated glomerular filtration rate (eGFR), an important measurement of kidney function, remained stable through month 30. There were no unexpected new adverse events reported in the voclosporin group compared to the control group.

“In this updated interim analysis, reductions in proteinuria were sustained with no impact on renal function at a total of 30 months of treatment with voclosporin,” said Amit Saxena, M.D., assistant professor, department of medicine at NYU Langone Medical Center and presenting author of the AURORA 2 study. “The consistent outcomes over time reinforce confidence in LUPKYNIS as an important treatment choice for people experiencing the dangerous manifestation of lupus nephritis.”

AURORA 2 (NCT03597464) is a Phase 3 randomized, double-blind, placebo-controlled clinical trial to assess the long-term safety and tolerability of voclosporin, in addition to the standard of care, for the treatment of LN in patients with SLE. Patients who completed 12

months of treatment in the Phase 3 AURORA 1 study were eligible to enroll in the AURORA 2 continuation study with the same randomized treatment of voclosporin at 23.7 mg twice daily or placebo, in combination with mycophenolate mofetil (MMF) at 1 g twice daily with either no or low-dose oral steroids, for an additional 24 months. A total of 216 LN patients continued into AURORA 2, with 116 patients in the voclosporin group and 100 patients in the control group. 90 and 78 patients, respectively, received 30 months of total treatment as of this interim analysis. Final results from the AURORA 2 study are expected by the end of 2021. Results from the completed Phase 3 randomized, double-blind, placebo-controlled, multicenter AURORA 1 study (NCT03021499) were recently published in [The Lancet](#).

“We are encouraged to see the continued positive outcomes with LUPKYNIS and look forward to seeing and presenting the complete results from AURORA 2 in the coming months,” said Neil Solomons, M.D., Chief Medical Officer at Aurinia.

About Lupus Nephritis

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 medicine for the treatment of adult patients with active lupus nephritis (LN). LUPKYNIS is a novel, structurally modified calcineurin inhibitor (CNI) with 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 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 recently introduced the first FDA-approved oral therapy indicated for the treatment of adult patients with active lupus nephritis (LN). Aurinia's head office is in Victoria, British Columbia; its U.S. commercial hub is in Rockville, Maryland; and the Company focuses 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 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 results of the updated interim AURORA-2 continuation study; and the planned timing for reporting top-line results from the ongoing AURORA-2 continuation study.

It is possible that such results or conclusions may change. 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 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: the market for the LN business may not be as estimated; unknown impact and difficulties imposed by the COVID-19 pandemic on Aurinia's business operations including nonclinical, clinical, regulatory and commercial activities; and the results from Aurinia's clinical studies and from third party studies and reports may not be accurate. Although Aurinia has 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 Aurinia's 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 press release 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 Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at 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, or on Aurinia's website at www.auriniapharma.com.

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