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Long Term Phase 3 Data Published in Arthritis & Rheumatology Shows LUPKYNIS® (voclosporin) Preserved Kidney Function Up to Three Years in Lupus Nephritis Patients with No New or Unexpected Adverse Events

EDMONTON, Alberta--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today announced that full results from the Phase 3, double-blind, placebo-controlled AURORA 2 extension study were published online in *Arthritis & Rheumatology*, the official peer-reviewed journal of the American College of Rheumatology.

As part of the AURORA Clinical Program, the AURORA 2 extension study assessed the long-term safety and tolerability of LUPKYNIS® (voclosporin), compared with placebo, in combination with mycophenolate mofetil and low-dose glucocorticoids, to treat active lupus nephritis (LN) in adult patients who completed one year of treatment in the Phase 3 AURORA 1 clinical trial.

Voclosporin was well tolerated with no new or worsening safety signals in the extension study. Clinical efficacy over three years of treatment was maintained, as observed by maintenance of urine protein creatinine ratio (UPCR) reductions, sustained complete renal response (CRR) and preserved kidney function, suggesting a positive benefit-risk profile for voclosporin in LN patients.

“Proteinuria, a defining part of the characterization of chronic kidney disease, often precedes a decline in kidney function and is associated with progression to kidney failure. Reductions in proteinuria are critical for slowing or stopping progression to end-stage kidney disease and improving long-term outcomes for LN patients. Notably, in this extension study, kidney preservation, sustained renal response, and reductions in steroid use were achieved with voclosporin. These findings demonstrate the critical importance of voclosporin in the management of LN to improve patient outcomes,” said lead study author Amit Saxena, MD, Division of Rheumatology, New York University Grossman School of Medicine.

Estimated glomerular filtration rate (eGFR), an important measurement of kidney function, remained stable throughout the extension study. The slope of the change in eGFR over the extension study period at month 36 demonstrated kidney function preservation in the voclosporin group (-0.2 mL/min/1.73m^2), compared with a decline in function after one year in the control group (-5.4 mL/min/1.73m^2).

There was a significant increase in achievement of CRR in LN patients treated with voclosporin, compared to patients in the control group, at nearly every time point in the AURORA Clinical Program. At month 12, CRR occurred in 52.6% of patients who received voclosporin, compared to 34.0% in the control group, largely driven by achieving a proteinuria reduction in UPCR to ≤0.5 mg/mg. At month 36, CRR occurred in 50.9% of patients who received voclosporin, compared to 39.0% of patients in the control group. CRR was defined as UPCR of ≤0.5 mg/mg, eGFR ≥60 ml/min/1.73 m^2 or no confirmed decrease from pretreatment baseline in eGFR of >20%, no rescue medication received for LN, and not receiving more than 10 mg of glucocorticoids for ≥3 consecutive days or for ≥7 days in total during the eight weeks prior to renal response assessment.

These results were achieved with most patients in both groups (>75%) maintaining glucocorticoid tapering throughout the study and receiving doses of ≤2.5 mg/day at the end of the extension study.

Of those who experienced adverse events (AEs) in the extension study, most were mild or moderate (86% in the voclosporin group vs. 81% in the control group). Across three years of treatment, infections were the most common type of AE (69.8% in the voclosporin group vs. 72.0% in the control group), with low rates of serious infections in both groups (12.9% in the voclosporin group vs. 17.0% in the control group). Most adverse events declined annually over the study period, with 86.1% of patients completing the two-year extension.

“The results of this extension study reinforce the long-term safety and effectiveness of LUPKYNIS to stabilize kidney function in those diagnosed with LN, a debilitating, yet common complication that occurs in about half of people with lupus,” said Dr. Greg Keenan, Chief Medical Officer of Aurinia. “Together, AURA-LV, AURORA 1, and AURORA 2 represent one of the largest and longest placebo-controlled clinical programs evaluating the treatment of LN. We are proud of our sustained research in autoimmune diseases like lupus and remain committed to helping improve kidney health for people living with lupus nephritis.”

About the AURORA Clinical Program

In AURORA 1 (NCT03021499), a 12-month, phase 3, double-blind, randomized-controlled pivotal study, the efficacy and safety of voclosporin was compared with a control group in achieving CRR in patients with LN. AURORA 1 demonstrated the clinical superiority of voclosporin with mycophenolate mofetil (MMF) and low-dose glucocorticoids compared to MMF and low-dose glucocorticoids alone. Significantly more patients in the voclosporin group achieved a CRR at 52 weeks of treatment and did so significantly faster than those in the control group. The safety profile in AURORA 1 was comparable between treatment groups, in line with previous studies; no new safety concerns were observed. Results from the completed Phase 3 randomized, double-blind, placebo-controlled, multicenter AURORA 1 study were published in *The Lancet*.

AURORA 2 (NCT03597464) is a Phase 3, double-blind, extension study to assess the long-term safety and tolerability of voclosporin, in addition to MMF and low-dose glucocorticoids, for the treatment of patients with active LN. Patients who completed 12 months of treatment in the Phase 3 AURORA 1 study were eligible to enroll in the AURORA 2 extension study with the same randomized treatment of voclosporin or placebo, in combination with MMF (target dose of 2 g/day) and low-dose glucocorticoids (target dose of ≤2.5 mg/day), for an

additional 24 months.

A total of 216 LN patients continued into the extension study, with 116 patients in the voclosporin group and 100 patients in the control group; 90 and 78 patients, respectively, received 36 months of total treatment at the completion of the study. Study drug dose changes decreased over time.

About Lupus Nephritis
Lupus Nephritis 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 about one-third of these people are diagnosed with lupus nephritis at the time of their SLE diagnosis. About 50 percent of all people with SLE may develop lupus nephritis. If poorly controlled, lupus nephritis can lead to permanent and irreversible tissue damage within the kidney. Black and Asian people with SLE are four times more likely to develop lupus nephritis and Hispanic people are approximately twice as likely to develop the disease, compared to White people with SLE. Black and Hispanic people with SLE also tend to develop lupus nephritis earlier and have worse outcomes, compared to White people with SLE.

About LUPKYNIS®
LUPKYNIS® is the first U.S. Food and Drug Administration and European Commission-approved oral medicine for the treatment of adult patients with active 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 Pharmaceuticals is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations with high unmet medical needs that are impacted by autoimmune, kidney and rare diseases. In January 2021, the Company introduced LUPKYNIS® (voclosporin), the first FDA-approved oral therapy dedicated to the treatment of adult patients with active lupus nephritis. The Company's head office is in Edmonton, Alberta, its U.S. commercial office is in Rockville, Maryland. 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 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.

References:
Saxena A., Ginzler E., Gibson K., Satirapoj B., Santillán A., Levchenko O., Navarra S., Atsumi T., Yasuda S., Chavez-Perez N., Arriens C., Parikh S., Caster D., Birardi V., Randhawa S., Lisk L., Huizinga R., Teng O. (2023), Safety and Efficacy of Long-Term Voclosporin Treatment for Lupus Nephritis in The Phase 3 AURORA 2 Clinical Trial. Arthritis Rheumatol. Accepted Author Manuscript: https://onlinelibrary.wiley.com/doi/abs/10.1002/art.42657

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Media Inquiries:
Andrea Christopher,
Corporate Communications Director, Aurinia
achristopher@auriniapharma.com

Investor Inquiries:
Aurinia@westwicke.com

Source: Aurinia Pharmaceuticals Inc.