May 9, 2023

Aurinia Pharmaceuticals Announces Kidney Biopsies Sub-study Data from the LUPKYNIS® (voclosporin) AURORA 2 Clinical Trial Presented at Congress of Clinical Rheumatology East Conference

First study to assess histologic changes in the kidneys of patients with lupus nephritis treated with LUPKYNIS® (voclosporin)

Treatment was not associated with chronic injury, with the average chronicity index remaining stable in both treatment arms from baseline to follow-up

Activity scores decreased in conjunction with improvements in urine protein creatinine ratio (UPCR) in both treatment arms

Data further reinforces differentiation of LUPKYNIS from first generation calcineurin inhibitors (CNIs)

EDMONTON, Alberta--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today announced data from the kidney biopsy sub-study of the AURORA clinical trial program (AURORA 1 and AURORA 2 Extension Study) was presented at the Congress of Clinical Rheumatology East Conference May 4 – 7, 2023.

The addition of LUPKYNIS to standard of care MMF and low-dose steroids in Aurinia's Phase 3 AURORA program led to significantly earlier and greater reductions in proteinuria while maintaining stable renal function, as evidenced by a stable estimated glomerular filtration rate (eGFR) slope over time.

To further characterize the long-term impact of LUPKYNIS on the kidney at the histologic level, repeat biopsies were collected from patients participating in the sub-study. Specifically, repeat renal biopsies were obtained from 16 patients in the LUPKYNIS arm and 10 patients in the active control arm over 18 months from study entry. Baseline and follow-up activity scores, a measure of active inflammation in LN, and chronicity scores, a measure of irreversible kidney injury, were obtained using a validated assessment tool.

"We are encouraged by these results," said Dr. Greg Keenan, Chief Medical Officer of Aurinia. "Seeing similar improvement in the activity scores and absence of change in the chronicity scores with the LUPKYNIS treated patients as compared to those on MMF and low dose steroids alone, without histologic findings of chronic CNI nephrotoxicity, strengthens the totality of the evidence supporting the long-term efficacy and safety of LUPKYNIS and further differentiates the safety of this second-generation treatment from the

legacy, first generation CNIs."

Higher rates of both complete renal response (CRR) and partial renal response (PRR) were observed in LUPKYNIS treated patients at month 36, consistent with the overall Aurora 2, LUPKYNIS treated population. The patients in the LUPKYNIS treatment arm demonstrated histologic activity improvement with stable chronicity scores similar to the active control arm of MMF and low dose steroids alone over the 18-months average treatment period at the time of repeat biopsy.

	Control / Standard of Care n=10		**LUPKYNIS (voclosporin)** n=16	
	Baseline*	**Follow-up**	**Baseline**	**Follow-up**
Activity Index, mean (SD)	**2.8 (3.2)**	**0.4 (1.0)**	**1.8 (3.0)**	**0.4 (1.0)**
Chronicity Index, mean (SD)	**2.9 (2.3)**	**2.8 (2.7)**	**3.8 (3.5)**	**4.1 (3.3)**
	Baseline	**Month 36**	**Baseline**	**Month 36**
UPCR, mean (SD), mg/mg	4.71 (2.6)	2.1 (4.6)	4.59 (2.5)	0.99 (1.4)
eGFR, mean (SD), mL/min/1.73m^2	82.6 (12.3)	85.8 (13.3)	80.3 (16.4)	82.7 (15.4)
CRR, % (n/n)	-	40.0 (4/10)	-	62.5 (10/16)
PRR, % (n/n)	-	70.0 (7/10)	-	81.3 (13/16)

*Data from pre-treatment baseline of AURORA 1.

There were no unexpected adverse events in patients treated with LUPKYNIS, and the safety profile was consistent with the overall AURORA 2 population.

LUPKYNIS is a novel calcineurin inhibitor (CNI) approved in the United States, European Union, and Great Britain for the treatment of adults with lupus nephritis (LN)[1]. It has two complementary mechanisms of action relevant to the treatment of LN and the inhibition of calcineurin[1]: it reduces activation of T-cells and stabilizes podocytes, reducing proteinuria. LUPKYNIS has a consistent dose-concentration relationship, eliminating the need for therapeutic drug monitoring[1,2] but unlike other CNIs, LUPKYNIS has shown no increased safety signal for diabetes or dyslipidemia, and has no drug-drug interaction with mycophenolate mofetil (MMF)[3-8].

The clinical poster presented at CCR East can be found by accessing the Aurinia corporate website contained within the Investor Relations tab and Presentation section of the site.

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 poorer outcomes, compared to White people with SLE.

About LUPKYNIS

LUPKYNIS® is the first U.S. FDA- and EC-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 a high unmet medical need 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.

1. LUPKYNIS® [package insert]. Rockville, MD : Aurinia Pharma U.S., Inc., 2021.
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5. van Gelder T et al. Nephrol Dial Transplant. 2021;gfab022.
6. Ardoin S et al. Kidney Int Rep. 2022;7:S99.
7. Rovin BH et al. Lancet. 2021 ;397(10289):2070-2080.
8. van Gelder T et al. Nephrol Dial Transplant. 2022 ;37(5):917-922.
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