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Aurinia Pharmaceuticals Announces Promising Topline Data from Renal Biopsy Sub-study of the AURORA Trial

LUPKYNIS® treated patients showed histologic activity improvement with stable chronicity scores similar to active control arm of mycophenolate mofetil (MMF) and low dose steroids alone

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

Conference call to be hosted today at 8:30 a.m. EDT

EDMONTON, Alberta--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today announced promising results from the AURORA Renal Biopsy Sub-Study. LUPKYNIS is a novel agent approved for the treatment of adults with active lupus nephritis (LN). The addition of LUPKYNIS on top of the then current standard of care MMF and low-dose steroids in Aurinia's Phase 3 AURORA 1 and AURORA 2 studies 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 selected patients in both treatment arms (the active control arm with patients treated with only MMF and steroids, and the study arm of voclosporin in combination with MMF and steroids). The patients in the voclosporin 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.

"We are encouraged by these results," said Dr. Greg Keenan, recently appointed 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 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."

Repeat renal biopsies were obtained from 16 patients in the voclosporin 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. Compared to baseline, the activity scores for both LUPKYNIS and active control populations improved to a similar degree, while the chronicity scores remained stable over time in both arms.

Dr. Brad Rovin, Professor of Nephrology and Director, Division of Nephrology at the Ohio

State University Wexner Medical Center said, “The lack of histologic evidence of CNI nephrotoxicity and the absence of progression of chronic kidney damage after approximately 18 months of treatment further strengthen the overall evidence supporting the long-term safety of LUPKYNIS in LN patients.”

Further data will be presented at the upcoming Congress of Clinical Rheumatology meeting, May 4-7, 2023. Aurinia will host a conference call/webcast at 8:30 am EDT to review these results. Interested participants can dial **877-407-9170 / +1 201-493-6756** (Toll-free U.S. & Canada). The audio and webcast can also be accessed under "News/Events” through the “Investors” section of the Aurinia corporate website at www.auriniapharma.com.

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.

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