Aurinia Pharmaceuticals Announces Presentations at American Society of Nephrology (ASN) Kidney Week 2023 and 2023 American College of Rheumatology Convergence (ACR)

EDMONTON, Alberta--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH) (“Aurinia” or the “Company”), a biopharmaceutical company committed to delivering therapeutics that change the trajectory of autoimmune disease, today announced that data from 14 studies of LUPKYNIS® (voclosporin) will be presented at the American Society of Nephrology (ASN) Kidney Week 2023, taking place November 2-5 in Philadelphia, Pennsylvania and at the 2023 American College of Rheumatology Convergence (ACR), taking place November 10-15 in San Diego, California.

Led by several leading experts in nephrology and rheumatology, these presentations reinforce the long-term safety and efficacy profile of LUPKYNIS® for the treatment of adults with active lupus nephritis (LN), a serious complication of systemic lupus erythematosus (SLE). The robust set of data demonstrates Aurinia’s deep commitment to sustained research in autoimmune diseases, including lupus.

The abstracts for ASN Kidney Week 2023 are listed below and available online at: https://www.asn-online.org/education/kidneyweek/2023/program-search-abstract.aspx

The abstracts for ACR 2023 are listed below and available online at: https://acrabstracts.org/

Aurinia will issue full data press releases at the time of the meetings.

ASN Kidney Week 2023 Oral and Poster Presentations:

**Title:** Repeat kidney biopsies from the AURORA 2 study of voclosporin in active lupus nephritis  
**Authors:** Samir V. Parikh, Clint Abner, Ernie Yap, Krista Piper, Rob Huizinga, Henry Leher  
**Date:** Thursday, November 2, 2023  
**Time:** 5:42 p.m. – 5:51 p.m. ET  
**Oral Session:** Glomerular Diseases - Clinical and Translational Studies  
**Location:** Room 103

**Title:** Urinary extracellular vesicles reveal distinct biological effects of voclosporin in the treatment of lupus nephritis  
**Authors:** Martijn H. van Heugten, Kuangyu Wei, Hester van Willigenburg, Faith Demir, Linda M. Rehaume, John Viel, Markus M. Rinschen, Ewout J. Hoorn
Date: Thursday, November 2, 2023  
Time: 10:00 a.m. – 12:00 p.m. ET  
Location: Poster Hall, #TH-PO550

Title: Registry of US adult patients with lupus nephritis treated with LUPKYNIS for lupus nephritis  
Authors: Lily Cipolla, Victoria Bal, Henry Leher  
Date: Friday, November 3, 2023  
Time: 10:00 a.m. – 12:00 p.m. ET  
Location: Poster Hall, #INFO16-FR

Title: Voclosporin treatment in adolescents with lupus nephritis (VOCAL)  
Authors: Nicola Waddingham, Amber Rosales, Gigi Cheung, Blake Potter, Mary Palmen  
(Presented by Ernie Yap)  
Date: Friday, November 3, 2023  
Time: 10:00 a.m. – 12:00 p.m. ET  
Location: Poster Hall, #INFO17-FR

Title: Long-term safety and efficacy of voclosporin in Black patients with lupus nephritis  
Authors: Gabriel Contreras, Matt Baker, Lucy Hodge, Ernie Yap  
Date: Saturday, November 4, 2023  
Time: 10:00 a.m. – 12:00 p.m. ET  
Location: Poster Hall, #SA-PO876

Title: Comparison of dual-immunosuppressive therapy and a voclosporin-based, triple-immunosuppressive regimen for lupus nephritis: a propensity analysis of ALMS and AURORA 1 studies  
Authors: Ernie Yap, Maria Dall’Era, Matt Truman, Lucy S. Hodge, Neil Solomons  
Date: Saturday, November 4, 2023  
Time: 10:00 a.m. – 12:00 p.m. ET  
Location: Poster Hall, #SA-PO877

Title: Comparative effects of cyclosporine and voclosporin on primary human proximal tubular epithelial (PTEC) gene expression  
Authors: Theresa Aliwarga, Linda M Rehaume, Catherine K Yeung, Jonathan Himmelfarb, Edward J Kelly  
Date: Saturday, November 4, 2023  
Time: 10:00 a.m. – 12:00 p.m. ET  
Location: Poster Hall, #TH-PO103

Title: Voclosporin ameliorates both proteinuria and dyslipidemia in a model of non-inflammatory glomerular disease  
Authors: Yu Kamigaki, Julie Dougherty, Amanda P. Waller, Linda M. Rehaume, Katelyn Wolfgang, Eman Abdelghani, Bryce A. Kerlin, William E. Smoyer  
Date: Saturday, November 4, 2023  
Time: 10:00 a.m. – 12:00 p.m. ET  
Location: Poster Hall, #SA-PO975

Title: Integrative systems analysis of calcineurin inhibitor action on podocytes and proximal tubular epithelial cells
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

INDICATION
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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20231013432160/en/

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