Aurinia Pharmaceuticals Announces Presentations at the 2022 ERA Congress and the 2022 EULAR Congress

VICTORIA, British Columbia--(BUSINESS WIRE)--

Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH) (Aurinia or the Company), a biopharmaceutical company committed to delivering therapeutics that change the course of autoimmune disease, today announced that data from multiple studies of LUPKYNIS™ (voclosporin) will be presented at the 59th European Renal Association (ERA) Congress and at the European Congress of Rheumatology, European Alliance of Associations for Rheumatology (EULAR) 2022. The 2022 ERA Congress will take place virtually and in Paris on May 19-22 and the EULAR 2022 Congress will take place virtually and in Denmark on June 1-4.

“Aurinia continues to expand its clinical evidence supporting LUPKYNIS as a reliable treatment option for people and HCPs working to protect their patients’ kidneys from the devastating impact of lupus nephritis,” said Neil Solomons, M.D., Chief Medical Officer at Aurinia. “We look forward to presenting new data for LUPKYNIS at the ERA and EULAR Congresses, including our results from the two-year AURORA 2 continuation study evaluating the long-term safety and tolerability of LUPKYNIS for the treatment of lupus nephritis.”

Scientific programs and information for the ERA Congress and EULAR Congress are available online at https://www.era-online.org/en/paris2022/ and https://congress.eular.org/index.cfm respectively. The presentation details are as follows.

**ERA Congress 2022 Presentations:**

**Title:** “Voclosporin for Lupus Nephritis: Results of the Two-year AURORA 2 Continuation Study”  
**Presenting author:** Y.K. Onno Teng, M.D., Ph.D., President of the National Foundation of the Autoimmune Research & Collaboration Hubs (ARCH)  
**Date:** Friday, May 20, 2022  
**Time:** 17:00-18:30 CEST

**Title:** “Early Reductions in Proteinuria with Voclosporin Treatment across Lupus Nephritis Biopsy Classes: Pooled Data from the AURA-LV and AURORA 1 Trials”  
**Presenting author:** Anca Askanase, M.D., M.P.H., Columbia University Medical Center  
**Date:** Friday, May 20, 2022  
**Time:** 17:43-17:58 CEST

**EULAR Congress 2022 Presentations and Posters:**
Title: “Voclosporin for Lupus Nephritis: Results of the Two-year AURORA 2 Continuation Study”

Presenting author: Amit Saxena, M.D., NYU School of Medicine

Date: Friday, June 3, 2022

Time: 12:26-12:34 CEST

Title: “Voclosporin is Effective in Achieving Proteinuria Treatment Targets in Lupus Nephritis Defined by EULAR/ERA Recommendations”

Presenting author: Hans-Joachim Anders, Professor of Nephrology and Head of Renal Division, University of Munich (LMU)

Date: Friday, June 3, 2022

Time: 10:30-12:00 CEST

LUPKYNIS is the first U.S. FDA-approved oral medicine for the treatment of adult patients with active lupus nephritis (LN). In June 2021, Aurinia, with its licensing partner, Otsuka Pharmaceutical Europe Ltd. (OPEL), filed an initial Marketing Authorization Application (MAA) for voclosporin for the treatment of lupus nephritis (LN) to the European Medicines Agency (EMA).

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 will 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 Pharmaceuticals 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. In January 2021, the Company introduced LUPKYNIS™ (voclosporin), the first FDA-approved oral therapy for the treatment of adult patients with active lupus nephritis (LN). The Company’s head office is in Victoria, British
Columbia; its U.S. commercial hub is in Rockville, Maryland; and the Company focuses its development efforts globally.

**Investor and Media:**

**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.


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