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Aurinia Pharmaceuticals Announces Presentations at the 2022 National Kidney Foundation Spring Clinical Meetings

Presentations include new analyses of AURORA 1 and details on the ENLIGHT-LN registry

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 2022 National Kidney Foundation Spring Clinical Meetings, taking place April 6-10, 2022 in Boston, Mass.

“Aurinia is committed to expanding the body of research supporting the clinical benefits of LUPKYNIS, the first FDA-approved oral therapy available to people living with lupus nephritis,” said Neil Solomons, M.D., Chief Medical Officer at Aurinia. “We look forward to sharing updates at the National Kidney Foundation’s Spring Clinical Meetings, including the design of a prospective observational registry of patients treated with LUPKYNIS.”

Abstracts are available online at: https://casehippo.com/spa/courses/resource/2022-spring-clinical-meetings/event/home/posters/browser

Presentations related to LUPKYNIS at the meetings include:

Title: “The Efficacy of Voclosporin in Lupus Nephritis is Independent of Changes in Anti-dsDNA and Complement at Week 52”
Poster number: 314
Presenting author: Betty Diamond, M.D., Director of the Institute of Molecular Medicine & Maureen and Ralph Nappi Professor of Autoimmune Diseases, Feinstein Institutes for Medical Research, Manhasset, New York

Title: “ENLIGHT-LN: A Prospective Observational Registry of Patients Treated with Voclosporin for Lupus Nephritis in the United States”
Poster number: 318
Presenting author: Keely Dahl, PharmD, Associate Medical Director, Aurinia Pharmaceuticals Inc.

Title: “Attainment of Complete Renal Response Results in Significant Improvements in Lupus Impact Tracker in the AURORA 1 Study of Voclosporin in Lupus Nephritis”
Poster number: 319
Presenting author: Meenakshi Jolly, M.D., M.S., Associate Professor, Rush University, Chicago

Title: “Confirmation of the Immunosuppressive Function of Voclosporin at the Clinically

Relevant Lupus Nephritis Dose in Lupus-prone Mice”
Poster number: 327
Presenting author: Linda M. Rehaume, Ph.D., Senior Research Scientist, Aurinia Pharmaceuticals Inc.

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 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 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 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.

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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