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Aurinia Pharmaceuticals Announces NICE Recommendation of LUPKYNIS® (Voclosporin) For Adults with Active Lupus Nephritis

EDMONTON, Alberta--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today announced that the National Institute for Health and Care Excellence (NICE) has recommended LUPKYNIS® (voclosporin) as an option for treating adults with active lupus nephritis (LN) class III, IV or V (including mixed class III/V and IV/V)[1], when provided in combination with mycophenolate mofetil (MMF).

The NICE recommendation applies to England and Wales and follows the recent Medicines and Healthcare Products Regulatory Agency (MHRA) authorization of voclosporin licensed in Great Britain for the treatment of active LN in adult patients.

“We are extremely pleased with the NICE recommendation of LUPKYNIS for patients with lupus nephritis. This recommendation follows the earlier approval from the MHRA and further supports access to an important treatment option for those patients. It also emphasizes Aurinia’s commitment to providing meaningful therapy for patients experiencing LN in key markets around the world,” said Peter Greenleaf, President, and Chief Executive Officer of Aurinia.

The NICE appraisal is based on the positive results from the pivotal Phase 3 AURORA-1 study[2,3] and the AURORA-2 continuation study[4], which demonstrated voclosporin, in combination with MMF and low-dose corticosteroids, led to statistically superior complete renal response rates at 52 weeks compared to MMF and low-dose corticosteroids alone, and maintained stable eGFR (estimated glomerular filtration rate) over 3 years. The safety profile of voclosporin and MMF and low-dose corticosteroids was generally comparable to MMF and low-dose corticosteroids alone.

About Lupus Nephritis

LN is a serious manifestation of 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, LN can lead to permanent and irreversible tissue damage within the kidney. Black and Asian people with SLE are four times more likely to develop LN and people of Hispanic ancestry are approximately twice as likely to develop the disease when compared with White people. Black and Hispanic people with SLE also tend to develop LN earlier and have poorer outcomes when compared to White people.

About LUPKYNIS

LUPKYNIS® is the first U.S. FDA- 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 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 for 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.

References

1. NICE. Voclosporin with mycophenolate mofetil for treating lupus nephritis [ID3962]. Available from: https://www.nice.org.uk/guidance/gid-ta10878/documents/html-content-5 (Last accessed: April 2023).
2. Rovin BH, Teng YKO, Ginzler EM, et al. Efficacy and safety of voclosporin versus placebo for lupus nephritis (AURORA 1): a double-blind, randomised, multicentre, placebo-controlled, phase 3 trial. Lancet. 2021;397(10289):2070–2080.
3. ClinicalTrials.gov. Aurinia Renal Response in Active Lupus With Voclosporin (AURORA). NCT03021499. Available from: https://clinicaltrials.gov/ct2/show/NCT03021499 (Last accessed: April 2023).
4. ClinicalTrials.gov. Aurinia Renal Assessments 2: Aurinia Renal Response in Lupus With Voclosporin (AURORA2), NCT03597464. Available from: https://clinicaltrials.gov/ct2/show/NCT03597464 (Last accessed: April 2023).

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