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Aurinia Pharmaceuticals Announces Swissmedic Approval of LUPKYNIS® (voclosporin)

EDMONTON, Alberta--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today announced that the Swiss Agency for Therapeutic Products (Swissmedic) has granted marketing authorization of LUPKYNIS® (voclosporin) in combination with a background immunosuppressive therapy to treat adults with active class III, IV and V (including mixed classes III/V and IV/V) lupus nephritis (LN), a serious complication of systemic lupus erythematosus (SLE). In addition, we have received Orphan Drug designation in Switzerland, granting 15 years of drug exclusivity protection in association with approval.

“We are extremely pleased with the Swissmedic approval of LUPKYNIS for adults with lupus nephritis. This approval provides patients with an important treatment option and makes LUPKYNIS a more accessible therapy for patients experiencing LN,” said Peter Greenleaf, President, and Chief Executive Officer, Aurinia. “Otsuka continues to be an important and valuable partner in our global efforts.”

The marketing authorization by Swissmedic, is based on the Phase 3 AURORA 1 study and the AURORA 2 continuation study, which demonstrated voclosporin, in combination with mycophenolate mofetil (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.

Aurinia and Otsuka Pharmaceutical Co., Ltd., (Otsuka) entered into a collaboration and licensing agreement in December 2020 for the development and commercialization of voclosporin for the treatment of LN in the United Kingdom, European Union, Japan, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein, and Ukraine.

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 for the treatment of adult patients with active lupus nephritis (LN). The Company's head office is in Edmonton, Alberta, 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 \leq 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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