Aurinia Presents Data Demonstrating LUPKYNIS® (voclosporin) is Effective in Achieving Proteinuria Treatment Targets in Lupus Nephritis Defined by EULAR/ERA Recommendations

-The post-hoc analysis based on the updated treatment recommendations was presented at the EULAR 2022 European Congress of Rheumatology

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, presented data demonstrating the efficacy of LUPKYNIS® (voclosporin) for the treatment of people with lupus nephritis (LN), a serious complication of systemic lupus erythematosus (SLE), in achieving the proteinuria treatment targets recommended by the European Alliance of Associations for Rheumatology (EULAR) and the European Renal Association (ERA). A post-hoc analysis of pooled data from the similarly designed 48-week AURA-LV and 52-week AURORA 1 studies were presented in an oral session at the EULAR 2022 European Congress of Rheumatology by Hans-Joachim Anders, M.D., Professor of Nephrology at the University of Munich (LMU).

The pooled analysis from the Phase 2 AURA-LV and Phase 3 AURORA 1 studies assessed the efficacy of voclosporin, in addition to mycophenolate mofetil (MMF) and low-dose steroids, to reduce urine protein creatinine ratio (UPCR) to achieve the following EULAR/ERA treatment targets updated in 2019: ≥25% reduction in UPCR by three months, ≥50% reduction in UPCR by six months, UPCR ≤0.7 mg/mg by 12 months, as well as steroid dose of ≤7.5 mg/day at 12 months.

The breakdown of the reductions in UPCR at month three, six, and 12 is as follows:

- At three months, 78.4% of patients in the voclosporin group and 62.4% of patients in the control group achieved ≥25% reduction in UPCR (OR 2.25, CI 1.52-3.33, p<0.0001).
- At six months, 66.0% of patients in the voclosporin group and 47.0% of patients in the control group achieved ≥50% reduction in UPCR (OR 2.24, CI 1.57-3.21, p<0.0001).
- At 12 months, 52.6% of patients in the voclosporin group and 33.1% of patients in the control group achieved UPCR ≤0.7 mg/mg (OR 2.52, CI 1.75-3.63, p<0.0001).

At 12 months, 89.6% of the voclosporin group and 82.8% of the control group achieved the recommended steroid dose of ≤7.5 mg/day according to the protocol-defined steroid taper
In addition, the proportion of patients meeting UPCR ≤0.7 and steroid dose ≤7.5 mg/day was 44.4% in the voclosporin group and 27.1% in the control group (OR 2.42, CI 1.66-3.53, p<0.0001).

“These data show that treatment with LUPKYNIS can help patients with lupus nephritis successfully achieve UPCR treatment targets as recommended by the European Alliance of Associations for Rheumatology and the European Renal Association - a high bar to achieve and clinically meaningful,” said Dr. Anders. “A treatment response meeting these proteinuria treatment targets increases the chance for better long-term kidney outcomes such as avoidance of kidney failure, dialysis or need for transplantation.”

“We are thrilled to see LUPKYNIS has met the European Alliance of Associations for Rheumatology and the European Renal Association’s guidelines indicated for UPCR treatment targets,” said Neil Solomons, M.D., Chief Medical Officer at Aurinia. “We’ve already demonstrated the many benefits of treatment with LUPKYNIS for patients with lupus nephritis through our studies at Aurinia, and analyses such as this one builds additional evidence and confidence for rheumatologists and nephrologists to offer patients this important treatment option.”

About AURORA 1

The AURORA 1 study was a 52-week study designed to evaluate the efficacy and safety of LUPKYNIS (23.7 mg twice daily) when added to background therapy of MMF and corticosteroids tapered to a low dose, compared to background therapy alone in an ethnically and racially diverse patient population with active LN. Three hundred fifty-seven patients with a diagnosis of SLE and LN according to the American College of Rheumatology criteria and a kidney biopsy within two years that showed Class III, IV and/or V LN were enrolled. AURORA 1 met its primary endpoint, achieving statistically superior complete renal response rates of 41% in the LUPKYNIS group versus 23% in the control group (odds ratio [OR] 2.65, 95% confidence interval [CI] 1.64-4.27; p < 0.0001). LUPKYNIS also achieved statistical significance in all pre-specified hierarchical secondary endpoints, including reduced time to 50% reduction from baseline in UPCR and time to UPCR <0.5 mg/mg compared to control. The primary endpoint was complete renal response at 52 weeks defined as urine protein creatinine ratio (UPCR) ≤0.5 mg/mg, with stable renal function (defined as estimated glomerular filtration rate [eGFR] ≥60 mL/min/1.73 m² or no confirmed decrease from baseline in eGFR of >20%), no administration of rescue medication, and no more than 10 mg prednisone equivalent per day for three or more consecutive days or for seven or more days during Weeks 44 through 52. LUPKYNIS was well tolerated with no unexpected safety signals. Serious adverse events (SAEs) were reported in 21% of those treated with LUPKYNIS and in 21% of those in the control group. Results from the completed AURORA 1 study (NCT03021499) were published in May 2021 in The Lancet.

About AURA-LV

The AURA–LV study (Aurinia Urinary protein Reduction in Active Lupus with Voclosporin) was a 48-week study comparing the efficacy of two doses of voclosporin added to current standard of care of MMF against standard of care with placebo in achieving CR in patients with active LN. All arms also received low doses of steroids as background therapy. Two hundred sixty-five patients were enrolled at centers in 20 countries worldwide. On entry to
the study, patients were required to have a diagnosis of LN according to established
diagnostic criteria (American College of Rheumatology) and clinical and biopsy features
indicative of highly active nephritis. The 24-week primary and secondary endpoints were
released in Q3 2016 where the primary and all secondary endpoints were met. Complete
remission (CR) is a composite endpoint that includes: confirmed UPCR of ≤0.5 mg/mg;
normal, stable renal function (≥60 mL/min/1.73m2 or no confirmed decrease from baseline in
eGFR of ≥20%); presence of sustained, low dose steroids (≤10mg prednisone from week
16-24); and no administration of rescue medications. Partial remission (PR) in the trial is
measured by a ≥50% reduction in UPCR with no concomitant use of rescue medication.

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 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.

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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Media:
Dana Lynch
Corporate Communications, Aurinia
dlynch@auriniapharma.com

Investors:
aurinia@westwicke.com

Source: Aurinia Pharmaceuticals Inc.