May 20, 2022

Aurinia Presents Results from the Two-Year AURORA 2 Continuation Study at the 2022 European Renal Association (ERA) Congress

Use of LUPKYNIS was safe and well tolerated in patients for up to three years of treatment, with no new safety signals

In AURORA 2, long-term treatment with LUPKYNIS led to a clinically relevant preservation of kidney function in LN patients

A pooled analysis from the AURA-LV and AURORA 1 studies, also presented at ERA, showed early treatment response to LUPKYNIS with reductions in proteinuria across lupus nephritis biopsy classes

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 presented for the first time the results of the AURORA 2 continuation study evaluating the long-term safety and tolerability of LUPKYNIS™ (voclosporin) for the treatment of adults with active lupus nephritis (LN), a serious complication in patients with systemic lupus erythematosus (SLE). The results were presented during an oral session at the 59th European Renal Association (ERA) Congress, held in Paris and virtually May 19-22, 2022.

The AURORA 2 study assessed long-term safety and tolerability of voclosporin compared to placebo (both taken in combination with mycophenolate mofetil (MMF) and low-dose oral steroids) in patients with LN receiving treatment for an additional 24 months following completion of one year on treatment in the AURORA 1 study. The primary endpoint was safety and included assessments of adverse events, deaths, and hematological assessments. Secondary endpoints include renal response, renal flare, renal outcomes, and changes in urine protein to creatinine ratio (UPCR) and estimated glomerular filtration rate (eGFR).

“Lupus nephritis is a severe complication of lupus that will occur in up to half of patients diagnosed with SLE,” said Y.K. Onno Teng, M.D., Ph.D., Leiden University Medical Center, Leiden, The Netherlands, presenting author of the AURORA 2 ERA presentation and principal study investigator. “These results demonstrated that patients on long-term voclosporin therapy continue to experience clinically relevant benefits, including significant preservation of kidney function long-term, with no unexpected, new safety signals.”

Voclosporin was well tolerated during the study period with a similar safety profile to control and no unexpected safety signals. Specific findings included:

- Overall rates of serious adverse events were similar in both the control (28.0%) and voclosporin (26.0%) arms and there was no increase in infectious events.
- Generally adverse events were low and decreased over time on treatment.
    - Significant and meaningful reductions in proteinuria achieved in AURORA 1 were maintained.
- In AURORA 2, there was a significant difference in eGFR slope in favor of voclosporin (-0.2 mL/min/1.73 m2) compared to control arm (-5.4 mL/min/1.73 m2).
- There was a small, expected, and early decrease in mean eGFR in the first four weeks of treatment in AURORA 1, after which eGFR remained stable through the end of AURORA 2.
- The mean UPCR was lower in the voclosporin-treated groups at all time points during the three years.
- There were four deaths in the active control group during AURORA 2, while none in the voclosporin-treated group.

“When treating patients with lupus nephritis, the ultimate goal is to preserve kidney function," said Neil Solomons, M.D., Chief Medical Officer at Aurinia. “We’re thrilled to build out the body of data that reinforces voclosporin as a safe and effective treatment option for lupus nephritis patients over the long term.”

A post-hoc analysis of pooled data from the AURA-LV and AURORA 1 studies was also presented during an oral session at the ERA Congress and examined the impact of voclosporin on the time to proteinuria reduction by biopsy class. The analysis reviewed pure class III, class IV, and class V biopsy groups and showed patients treated with voclosporin in addition to MMF and low dose steroids achieved earlier reductions in proteinuria across biopsy classes. These results support the efficacy results observed in the AURA-LV and AURORA 1 trials respectively, indicating a faster time to response when voclosporin is added to MMF and low-dose steroid treatment.

“The breadth of the AURORA clinical program provides important insights demonstrating the efficacy of voclosporin for the treatment of lupus nephritis across varying patient types," said Anca Askanase, M.D., M.P.H., Columbia University Medical Center and presenting author of the AURA-LV and AURORA 1 pooled analysis. "This analysis strengthens the clinical evidence supporting voclosporin as an important option that physicians can use in addition to the current standard of care treatment regimen to rapidly control lupus nephritis and protect kidney function.”

AURORA 2 Study Design

AURORA 2 (NCT03597464) is a Phase 3 randomized, double-blind, placebo-controlled clinical trial to assess the long-term safety and tolerability of voclosporin, in addition to MMF/steroids. Patients who completed 12 months of treatment in the Phase 3 AURORA 1 study were eligible to enroll in the AURORA 2 continuation study with the same randomized treatment of voclosporin at 23.7 mg twice daily or placebo, in combination with MMF at 1 g twice daily with low-dose oral steroids, for up to an additional 24 months. A total of 216 LN patients continued into AURORA 2, with 116 patients in the voclosporin-treated group and 100 patients in the active control group.

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 m^2 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. 265 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 LN at the time of their SLE diagnosis. About 50 percent of all people with SLE may go on to 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 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.

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.