May 10, 2021

Aurinia Announces Publication of AURORA 1 Phase 3 Study Results with LUPKYNIS™ (voclosporin) in The Lancet

Study results demonstrate that LUPKYNIS in combination with typical standard of care (SoC) led to statistically superior complete renal response rates compared to treatment with SoC alone

VICTORIA, British Columbia & ROCKVILLE, Md.--(BUSINESS WIRE)--Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX: AUP) ("Aurinia" or the "Company") today announced that *The Lancet*, an international, peer-reviewed medical journal, published the results of the Company's Phase 3 AURORA 1 study evaluating LUPKYNIS (voclosporin) in adults with lupus nephritis (LN). The AURORA 1 study results demonstrate that LUPKYNIS in combination with mycophenolate mofetil (MMF) and low-dose corticosteroids led to statistically superior complete renal response rates at 52 weeks compared to treatment with MMF and low-dose corticosteroids alone, with a comparable safety profile. In fact, separation in efficacy between treatment groups was observed as early as 4 weeks. MMF and corticosteroids are typical SoC immunosuppressive agents used for the treatment of LN. On January 22, 2021, the U.S. Food and Drug Administration (FDA) approved LUPKYNIS in combination with a background immunosuppressive therapy regimen to treat adult patients with active LN.

"Lupus nephritis can be a devastating condition if not diagnosed and managed early," stated Brad H. Rovin, M.D., Professor of Medicine and the Director of the Division of Nephrology, Ohio State University Wexner Medical Center, an AURORA clinical trial investigator and the lead author of the publication. "The publication of AURORA 1 data validates the importance of voclosporin (LUPKYNIS) in early disease intervention for LN. These data establish voclosporin as an efficacious and safe, rapid-acting new treatment option for patients in need."

The published AURORA 1 results are based on the global Phase 3 randomized, double-blind, placebo-controlled study (NCT03021499) designed to evaluate the efficacy and safety of LUPKYNIS (23.7 mg twice daily) when added to background therapy of MMF and low-dose corticosteroids, compared to background therapy alone in an ethnically and racially diverse patient population with active LN.

The AURORA 1 study enrolled 357 patients with a diagnosis of systemic lupus erythematosus (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. 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. Key secondary hierarchical endpoints were complete renal response (CR) at Week 24 (based on primary endpoint definition with steroid dosing assessed during Weeks 16 through 24), partial renal response (PR), defined as a 50% reduction in UPCR from baseline, at Weeks 24 and 52, time to UPCR of ≤0.5 mg/mg and time to 50% reduction in UPCR from baseline.

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 improved time to 50% reduction from baseline in UPCR or and time to UPCR <0.5 mg/mg compared to control. The robustness of the data was also supported by all pre-specified subgroup analyses (age, sex, race, biopsy class, region and MMF use at screening) favoring LUPKYNIS.

LUPKYNIS was well tolerated with no unexpected safety signals. Serious adverse events (SAEs) were reported in 21% of those treated with LUPKNYIS and in 21% of those in the control group. Infection and infestations were the most commonly reported SAEs, in 10% of the LUPKYNIS group and 11% of the control group. Overall mortality in the AURORA 1 trial was low, with six deaths observed; one in the LUPKYNIS group and five in the control group. Additionally, the LUPKYNIS group showed no notable decrease at Week 52 in mean eGFR or increase in mean blood pressure, lipids or glucose, which are common adverse events associated with traditional calcineurin inhibitors (CNIs).

“The FDA approval of LUPKYNIS and the publication of the AURORA 1 results support and underscore our efforts to improve the health outcomes of people living with the devastating impacts of LN,” said Robert Huizinga, Ph.D. R.N., Executive Vice President of Research, Aurinia. “It is the culmination of many years of research both within Aurinia and with investigators and patients and we look forward to continuing our research with this important compound, and to sharing longer-term safety and efficacy data from the ongoing AURORA 2 continuation study in the coming months.”

About Lupus Nephritis

LN is a serious progression of 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 have already developed LN at the time of SLE diagnosis. 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 with 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 treatment for the treatment of adult patients with active LN. A novel, structurally modified CNI, LUPKYNIS has 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-serum drug monitoring required. 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 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. The company recently introduced the first FDA-approved oral therapy dedicated for the treatment of adult patients with active lupus nephritis (LN). Aurinia's head office is in Victoria, British Columbia, its U.S. commercial hub is in Rockville, Maryland, and development efforts are focused 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 calcineurin inhibitors (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 m^2 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.

Forward-Looking Statements

Certain statements made in this press release may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include but are not limited to statements or information with respect to: Aurinia's estimates as to the number of patients with SLE in the U.S. and the proportion of those persons who will develop LN; and the proportion of Black and Asian individuals, and individuals with Hispanic ancestry, compared to Caucasian individuals, to develop LN. It is possible that such results or conclusions may change based on further analyses of these data. Words such as "anticipate", "will", "believe", "estimate", "expect", "intend", "target", "plan", "goals", "objectives", "may" and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: the accuracy of the results from our clinical trials; and the accuracy of reported data from third party studies and reports. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

Forward-looking information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following difficulties we may experience in completing the commercialization of voclosporin; the market for the LN business may not be as estimated; and the results from our clinical studies and from third party studies and reports may not be accurate. Although we have attempted to identify factors that would cause actual actions, events or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond our control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information.

All forward-looking information contained in this presentation is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business, can be found in Aurinia's most recent annual report on Form 10-K available by accessing the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at www.sec.gov/edgar or the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at www.sedar.com.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20210510005063/en/

Investors:

Glenn Schulman, PharmD, MPH
Investor Relations & Corporate Communications, Aurinia
gschulman@auriniapharma.com

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

Media:
Marin Bergman
Ten Bridge Communications
marin@tenbridgecommunications.com

Source: Aurinia Pharmaceuticals Inc.