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Aurinia Presents Additional AURORA Pivotal Trial Safety Data at the ERA-EDTA Virtual Congress 2020

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (Nasdaq:AUPH / TSX:AUP) ("Aurinia" or the "Company"), a late-stage clinical biopharmaceutical company focused on advancing voclosporin across multiple indications, announced that additional safety data from the completed AURORA pivotal trial of voclosporin were shared at the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) 2020 Virtual Congress in an oral presentation given by nephrologist Dawn Caster, M.D., Assistant Professor of Medicine at the University of Louisville School of Medicine.

The data showed that pre-specified confirmed estimated glomerular filtration rate (eGFR) decreases of over 30% were similar in both AURORA trial patient groups, with 10.1% reported in the voclosporin group and 10.2% in the control arm ($p=0.971$). eGFR is a standard measure of kidney function. No clinically meaningful differences between the treatment (23.7 mg twice daily oral voclosporin) and control groups were seen at any timepoints in the study on this parameter or in serum creatinine levels, another biomarker for renal damage. All patients in the AURORA study were treated with mycophenolate (MMF) and a background of corticosteroids. MMF is considered the standard-of-care for lupus nephritis, although unapproved by the FDA for that use.

"This important new aspect of the full AURORA results further adds to the existing dataset that shows voclosporin's benefit over the standard-of-care with no apparent safety penalty," said Neil Solomons, M.D., Chief Medical Officer of Aurinia. "Our deep analysis of the comprehensive voclosporin clinical program continues to illustrate its potential as a treatment for lupus nephritis. This data has been submitted to the FDA as part of voclosporin's recently completed New Drug Application."

As previously reported, AURORA met its primary endpoint, achieving statistically superior Renal Response rates of 40.8% for voclosporin versus 22.5% for the control (OR 2.65, 95% CI; $p < 0.001$). The benefits of voclosporin were also seen for all prespecified hierarchical secondary endpoints, achieving statistical significance in favor of voclosporin for Renal Response at 24 weeks, Partial Renal Response at 24 and 52 weeks, time to achieve urinary protein-to-creatinine ratio (UCPR) ≤ 0.5 , and time to 50% reduction in UPCR.

Voclosporin was well tolerated with no unexpected safety signals. Serious adverse events (SAEs) were reported in 20.8% of voclosporin patients versus 21.3% in the control arm. Infection was the most commonly reported SAE with 10.1% of voclosporin patients versus 11.2% of patients in the control arm. Overall mortality in the trial was low, with six deaths observed; one in the voclosporin arm and five in the control group. Additionally, the voclosporin arm showed no significant decrease at week 52 in eGFR or increase in blood pressure, lipids or glucose, which are common adverse events associated with legacy calcineurin inhibitors (CNIs).

About Voclosporin

Voclosporin, an investigational drug, is a novel and potentially best-in-class calcineurin inhibitor (CNI) with clinical data in over 2,600 patients across indications. Voclosporin is an immunosuppressant, with a synergistic and dual mechanism of action. By inhibiting calcineurin, voclosporin blocks IL-2 expression and T-cell mediated immune responses and stabilizes the podocyte in the kidney. It has been shown to have a more predictable pharmacokinetic and pharmacodynamic relationship (potentially requires no therapeutic drug monitoring), an increase in potency (versus cyclosporine A), and an improved metabolic profile compared to legacy CNIs. Aurinia anticipates that upon regulatory approval, patent protection for voclosporin will be extended in the United States and certain other major markets, including Europe and Japan, until at least October 2027 under the *Hatch-Waxman Act* and comparable laws in other countries and until April 2028 with anticipated pediatric extension. Further, a U.S. patent has also been issued covering the voclosporin dosing protocol with a term extending to December 2037, if the FDA incorporates the dosing protocol used in both the AURA and AURORA trials into the product label.

About Lupus Nephritis

Lupus nephritis (LN) is an inflammation of the kidney caused by Systemic Lupus Erythematosus (SLE) and represents a serious progression of SLE. SLE is a chronic, complex and often disabling disorder. The disease is highly heterogeneous, affecting a wide range of organs and tissue systems. Unlike SLE, LN has straightforward disease outcomes, where an early reduction in proteinuria correlates with positive long-term outcomes. In patients with LN, renal damage results in proteinuria and/or hematuria and a decrease in renal function as evidenced by reduced eGFR, and increased serum creatinine levels. LN is debilitating and costly and if poorly controlled, LN can lead to permanent and irreversible tissue damage within the kidney, resulting in end-stage renal disease (ESRD), thus making LN a serious and potentially life-threatening condition.

About Aurinia

Aurinia Pharmaceuticals is a late-stage clinical biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are impacted by serious diseases with a high unmet medical need. The Company is currently developing the investigational drug voclosporin for the treatment of lupus nephritis, other proteinuric diseases and dry eye syndrome. The Company's head office is in Victoria, British Columbia, its U.S. commercial hub in Rockville, Maryland, and focuses its development efforts globally.

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, information or public presentations with respect to: positive efficacy and safety results from the AURORA Phase 3 pivotal trial, the full AURORA dataset, additional safety data, voclosporin as having Statistical Superiority Over Standard of Care in Lupus Nephritis and voclosporin's differentiation from legacy calcineurin inhibitors; completing NDA rolling submissions and filings in a quality, successful and timely manner; having the FDA accept the filing and grant Priority Review, shortening the review time to 8 months instead of 12; the potential for commercial launch of voclosporin for use in LN in 2021; efforts towards delivering the first FDA-approved treatment option for those affected by LN in the hope of changing the course of this disease; timeline challenges due to the COVID-19 outbreak; voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity; Aurinia's anticipation that upon regulatory approval, patent protection for voclosporin composition of matter will be extended in the United States and certain other major markets, including Europe and Japan, until at least October 2027 under the Hatch-Waxman Act and comparable laws in other countries and until April 2028 with anticipated pediatric extension; a US patent has also been issued covering the voclosporin dosing protocol with a term extending to December 2037, if the FDA incorporates the dosing protocol used in both the AURA and the AURORA studies into the product label; that the results of the AURORA clinical study are pivotal and a potential game changer for LN patients; that voclosporin may be positioned to become the standard of care for people living with LN; that Aurinia will present AURORA study results at a future scientific conference during 2020. 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 market value for the LN and DES programs; that another company will not create a substantial competitive product for Aurinia's LN and DES business without violating Aurinia's intellectual property rights; the burn rate of Aurinia's cash for operations; the costs and expenses associated with Aurinia's clinical trials; the planned studies achieving positive results; Aurinia being able to extend and protect its patents on terms acceptable to Aurinia; and the size of the LN, DES or proteinuric kidney disease markets; Aurinia will be able to obtain all necessary regulatory approvals for commercialization of voclosporin for use in LN on terms that are acceptable to it and that are commercially viable; and that Aurinia's intellectual property rights are valid and do not infringe the intellectual property rights of other parties. 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, delays, or failures we may experience in the conduct of our clinical trial; difficulties we may experience in completing the development and commercialization of voclosporin; the market for the LN, DES and other proteinuric kidney disease business may not be as estimated; Aurinia may have to pay unanticipated expenses; estimated costs for clinical trials may be underestimated, resulting in Aurinia having to make additional expenditures to achieve its current goals; Aurinia not being able to extend or fully protect its patent portfolio for voclosporin; competitors may arise with similar products; Aurinia may not be able to obtain necessary regulatory approvals for commercialization of voclosporin in a timely fashion, or at all; and Aurinia may not be able to obtain sufficient supply to meet commercial demand for voclosporin in a timely fashion. 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.

Except as required by law, Aurinia will not update forward-looking information. All forward-looking information contained in this press release 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 Information Form available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at www.sedar.com or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at www.sec.gov/edgar.

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