Aurinia Announces AURORA Phase 3 Clinical Data for Voclosporin in Lupus Nephritis to be Presented at National Kidney Foundation 2020 Spring Clinical Meetings

- Data to be shared as a late-breaking oral presentation during the live virtual NKF conference -

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 in multiple indications, today announced that clinical data from its AURORA Phase 3 trial will be highlighted in a late-breaking oral presentation during the National Kidney Foundation (“NKF”) 2020 Spring Clinical Meetings, which will be held as a live-virtual meeting per recommendations by the Centers for Disease Control and Prevention (“CDC”). The AURORA pivotal trial evaluated voclosporin in combination with mycophenolate (“MMF”) and low-dose corticosteroids for the treatment of lupus nephritis (“LN”).

Aurinia previously announced positive efficacy and safety results from the AURORA Phase 3 pivotal trial in December 2019. These data will be submitted as part of the rolling submission for the voclosporin new drug application (“NDA”), which the Company expects to complete by the end of the second quarter of 2020.

Full Presentation Details

Title: Aurora Phase 3 Trial Demonstrates Voclosporin Statistical Superiority Over Standard of Care in Lupus Nephritis (LN)  
Session: Late-Breaking Abstract Presentations  
Presenter: Keisha Gibson, M.D., Ph.D., University of North Carolina School of Medicine, Chapel Hill, NC  
Date: Thursday, March 26, 2020; 4:15 p.m. – 4:45 p.m. CT

Following the session, a reprint of the slide presentation will be accessible from Aurinia’s website at: https://ir.auriniapharma.com/presentations.

About AURORA

The AURORA Phase 3 clinical trial is a global, double-blind, placebo-controlled study to evaluate whether voclosporin when added to background therapy of mycophenolate mofetil
CellCept® can increase speed of and overall renal response rates in the presence of low dose steroids. The primary endpoint for the study is complete renal response at 52 weeks, after which patients can choose to enroll into a 104-week blinded extension study. Renal response was defined as UCPR of ≤ 0.5 mg/mg, eGFR ≥ 60 mL/min/1.73 m², or no confirmed decrease from baseline in eGFR of > 20%, presence of sustained, low dose steroids and no administration of rescue medication. The target enrollment of 324 patients was surpassed with a total of 357 lupus nephritis (LN) patients randomized globally across sites in 27 countries.

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 (measuring proteinuria) where an early response correlates with 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 clinical-stage 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 an investigational drug, for the treatment of lupus nephritis, focal segmental glomerulosclerosis and dry eye syndrome. The Company’s head office is in Victoria, British Columbia and focuses its development efforts globally. For further information, see our website at www.auriniapharma.com.

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: positive efficacy and safety results from the AURORA Phase 3 pivotal trial, completing NDA priority review submissions in a successful and timely manner including a rolling submission and the anticipated NDA filing during the first half of 2020; the potential for commercial launch of voclosporin for use in LN in 2021; 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, DES and FSGS programs; that
another company will not create a substantial competitive product for Aurinia’s LN, DES and FSGS 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 FSGS 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 FSGS 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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