Aurinia Completes Voclosporin Drug-Drug Interaction Study Demonstrating No Clinically Significant Interaction With Mycophenolate Mofetil

- Data support differentiation of voclosporin as a potential best-in-class CNI -

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 inflammatory and autoimmune conditions, today announced the completion of a FDA-requested clinical drug-drug interaction (“DDI”) study in patients with lupus that investigated the potential effect of voclosporin on blood levels of mycophenolate acid (“MPA”), the active metabolite of mycophenolate mofetil (“MMF”). MMF, also known as CellCept®, is considered by treating physicians to be part of the current standard of care for lupus nephritis (“LN”) in the United States.

“These results support our belief that voclosporin has no clinically significant impact on MPA levels. These data give us further confidence that the addition of voclosporin to MMF and corticosteroids for the treatment of LN can lead to predictable immunomodulation therapy and optimal results for people suffering from this devastating autoimmune disorder,” commented Neil Solomons, M.D., Chief Medical Officer at Aurinia.

This FDA-requested clinical DDI study aimed to measure, and potentially quantify, the impact voclosporin may have on MPA blood levels when given concomitantly with MMF in patients with lupus. The study results indicate that the coadministration of voclosporin with MMF had no clinically significant impact on MPA blood concentrations. In past studies, it was reported that the legacy calcineurin inhibitors (“CNIs”) inhibit the multidrug-resistance-associated protein 2 (MRP-2) transporter in the biliary tract thereby preventing the excretion of mycophenolic acid glucuronide (MPAG) into the bile leading to the enterohepatic recirculation of MPA\(^1\). This adverse impact of cyclosporine on MPA pharmacokinetics has resulted in a 30 – 50\% reduction in MPA exposure when used in combination\(^1\).

“These DDI study results further enhance our understanding of voclosporin’s differentiated profile, and we look forward to submitting these data, along with the results from the AURORA Phase 3 trial next year as part of our NDA submission,” stated Peter Greenleaf, Chief Executive Officer of Aurinia.

Aurinia remains on track to report results from the AURORA Phase 3 in LN trial by the end of this year. AURORA is a global, randomized, 52-week double-blind, placebo-controlled Phase 3 study that compares the efficacy of voclosporin versus placebo when added to
MMF and corticosteroids in subjects with active LN. The results of AURORA are intended to support marketing approval of voclosporin for patients with LN across multiple regulatory jurisdictions.

1. *CellCept® (mycophenolate mofetil) package insert*, Genentech USA, Inc., A Member of the Roche Group, 1 DNA Way, South San Francisco

**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](http://www.auriniapharma.com).
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 (vs cyclosporin), 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, the new Notice of Allowance is expected to result in the issuance of a U.S. patent with a term extending to December 2037. If the FDA approves the use of voclosporin for LN and the label for such use follows the dosing protocol under the Notice of Allowance, the issuance of this patent will expand the scope of intellectual property protection for voclosporin to December 2037.

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: the results and impact the DDI study will have with regulators or potential approval of voclosporin for LN, the ability to fully-enroll and report top-line results from the AUDREY clinical trial during the second half of 2019, and the number of subjects expected to be enrolled; completing NDA submissions in a successful and timely manner including the anticipated NDA filing during the first half of next year and subsequent commercial launch in 2021, voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity; the anticipated AUDREY clinical study including enrolling the first subject in the fourth quarter of 2019 and the number of subjects expected to be enrolled; the expected timing of FSGS results and patient enrollment; and that Aurinia has sufficient financial resources to fund the existing LN program, including the AURORA trial, and the NDA submission to the FDA, conduct the current Phase 2a study for FSGS, commence additional studies for DES and fund operations into the second half of 2020. Aurinia’s expected use of the funds from the ATM offering; Aurinia’s anticipation 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; that the new Notice of Allowance is expected to result in the issuance of a U.S. patent with a term extending to December 2037; that if the FDA approves the use of voclosporin for LN and the label for such use follows the dosing protocol under the Notice of Allowance, the issuance of this patent will expand the scope of intellectual property protection for voclosporin to December 2037. 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. 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; and competitors may arise with similar products. 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.

We seek Safe Harbor.

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