

October 22, 2020



# **Aurinia Presents Voclosporin Efficacy and Pharmacokinetic Data from Integrated Analysis of AURA-LV and AURORA Pivotal Trials at ASN Kidney Week 2020**

*- Integrated analysis confirms statistically superior efficacy and safety of voclosporin in combination with MMF and steroids over standard-of-care –*

*- Voclosporin pharmacokinetic data supports consistent dose-response, potentially eliminating the need for therapeutic drug monitoring –*

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, today announced that integrated efficacy and pharmacokinetic (PK) data from Aurinia’s AURA-LV and AURORA pivotal trials of voclosporin in lupus nephritis (LN) were presented. The data were shared at the American Society of Nephrology (ASN) Kidney Week 2020 in presentations given by Brad Rovin, M.D., FASN, Director of Nephrology and Vice Chairman of Research for the Department of Internal Medicine at the Ohio State University Wexner Medical Center and Teun van Gelder, Professor in Clinical Pharmacology for the Department of Clinical Pharmacy and Toxicology at the Leiden University Medical Center.

“People living with lupus nephritis are in a race against time to get their disease under control with the goal of improving their long term kidney health. We are pleased that the pooled analysis from our AURA-LV and AURORA pivotal trials further underscores voclosporin’s potential as an important tool to help people quickly change the course of their disease,” said Neil Solomons, M.D., Chief Medical Officer of Aurinia. “Together with the supportive pharmacokinetic data, these findings add to the growing body of information available on voclosporin as an investigational drug that could provide an important treatment approach for people dealing with LN.”

Data from a total of 534 patients from AURA-LV and AURORA was integrated and presented, demonstrating that 268 patients with LN treated with voclosporin in combination with mycophenolate mofetil (MMF) and low-dose steroids achieved statistically superior and faster Renal Response rates compared to 266 patients treated with MMF and steroids alone. The effects were also observed in Hispanic patients, a high-risk lupus nephritis population. Treatment with voclosporin resulted in clinically meaningful and a statistically significant higher Renal Response rate of 43.7% compared to 23.3% in the control arm at one year (OR 2.76, 95% CI: 1.88, 4.05;  $p < 0.0001$ ) and at six months (voclosporin 31.7%; placebo 20.3%), [OR: 2.01; 95% CI: 1.34, 3.01;  $p=0.0008$ ].

The Company also presented PK data analyzed from the AURA-LV and AURORA studies

further supporting the potential to eliminate the need for therapeutic drug monitoring. The influence of various covariates on voclosporin's PK was evaluated based on a population PK model and calcineurin inhibition was estimated using concentration data in the LN population and previously measured inhibition. At the recommended therapeutic dose of 23.7 mg twice daily, sex, body weight, race, age, serum albumin, total bilirubin and estimated glomerular filtration rate (eGFR) demonstrated no clinically relevant effect on voclosporin's PK parameters. Voclosporin was shown to inhibit calcineurin in a dose-dependent manner. In a quartile exposure analysis, no relationship with the odds ratio for renal response was observed and favored voclosporin in all quartiles. The linear PK profile of voclosporin allows the use of a pharmacodynamic approach instead of a pharmacokinetic approach, in which the dose of voclosporin is adjusted in response to decreases in eGFR.

The AURA-LV and AURORA studies were of similar design and conducted in comparable patient populations. The data from both studies for subjects treated with the recommended voclosporin dose of 23.7 mg twice daily (AURORA; n=179, AURA-LV; n=89) or with matching placebo (AURORA; n= 178, AURA-LV; n=88) were therefore pooled for an integrated analysis.

The data presented at ASN Kidney Week 2020 was submitted as part of voclosporin's new drug application (NDA) to the United States Food and Drug Administration (FDA). The FDA accepted the NDA, agreed to Priority Review, and has assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 22, 2021.

## **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 seeking FDA approval of voclosporin for the potential treatment of LN and evaluating voclosporin ophthalmic solution in a Phase 2/3 study for the treatment of dry eye syndrome. The Company's head office is in Victoria, British Columbia and its U.S. commercial hub is in Rockville, Maryland. The Company 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 or information with respect to: the Company's belief that the voclosporin efficacy and PK data from the integrated analysis of the AURA-LV and AURORA studies supports consistent dose-response, has the potential to eliminate the need for therapeutic drug monitoring, underscores voclosporin as a potentially important tool to help people quickly change the course of their disease, and could provide an important treatment approach for people dealing with LN; the Company's PDUFA target action date of January 22, 2021; and the potential FDA approval of voclosporin as a potential treatment for 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 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; Aurinia may not be able to obtain sufficient supply to meet commercial demand for voclosporin in a timely fashion; the unknown impact and difficulties imposed by the COVID-19 pandemic on our business operations including nonclinical, clinical, regulatory and commercial activities; and our assets or business activities may be subject to disputes that may result in litigation or other legal claims.. 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](http://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](http://www.sec.gov/edgar).

*We seek safe harbour.*

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20201022006147/en/>

**Investors & Corporate:**

Glenn Schulman, PharmD, MPH  
Corporate Communications, Aurinia  
[gschulman@auriniapharma.com](mailto:gschulman@auriniapharma.com)

**Media**

Stefan Riley  
Ten Bridge Communications  
[stefan@tenbridgecommunications.com](mailto:stefan@tenbridgecommunications.com)

Source: Aurinia Pharmaceuticals Inc.