

November 16, 2016



# Aurinia Highlights Speed of Remission from Global Phase IIb AURA Study of Voclosporin in Lupus Nephritis at 2016 American College of Rheumatology Annual Meeting

*Late breaking abstract showcases first global study of active lupus nephritis to meet its primary endpoint, presented on November 15<sup>th</sup>*

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH) (TSX:AUP) ("Aurinia" or the "Company"), a clinical stage biopharmaceutical company focused on the global immunology market, today highlighted additional findings from its global Phase IIb AURA study of voclosporin in the treatment of lupus nephritis (LN). The abstract was presented at the American College of Rheumatology and Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in Washington, D.C. during the Late-Breaking News session on November 15, 2016.

The late-breaking abstract, titled, "Speed of Remission with the Use of Voclosporin, MMF and Low Dose Steroids: Results of a Global Lupus Nephritis Study," was presented by Mary Anne Dooley, M.D., M.P.H., of the University of North Carolina Kidney Center. The global Phase IIb AURA study of voclosporin, a novel immunosuppressant that has been applied as a treatment for LN, is the first global active lupus nephritis study to meet its primary endpoint. In addition, all secondary endpoints in AURA were met, including demonstrating a more rapid response rate for patients receiving voclosporin versus patients in the control arm with most patients achieving complete remission (CR) at or before the eighth week of the trial.

"Lupus nephritis is a devastating, often overlooked disease that severely impacts a patient's quality of life and, in the worst cases, can lead to end-stage renal disease or even death," said Dr. Dooley. "The ability to get more patients into remission and in a shorter period of time than the current standard of care can have a significant impact on the long-term outcomes for these patients. We have demonstrated that voclosporin successfully achieves not only higher complete remission rates but does so more rapidly in patients with LN. I believe this promising data has the potential to shift the standard of care and improve long-term outcomes for patients with LN."

---

**Speed of Remission Analyses**

**Control**

**Voclosporin  
23.7mg BID**

---

|                                                                                 |              |                              |
|---------------------------------------------------------------------------------|--------------|------------------------------|
| <b>Post-hoc Responder Analysis</b> (Median time to CR for those who achieve CR) | 12 weeks     | 7.3 weeks                    |
| <b>Pre-Specified Endpoint: Time to Complete Remission (TTCR)</b><br>[median]    | Not achieved | 19.7 weeks<br><i>p</i> <.001 |
| <b>Pre-Specified Endpoint: Time to Partial Remission (TTPR)</b><br>[median]     | 6.6 weeks    | 4.1 weeks<br><i>p</i> =.002  |

“This promising data emphasizes the importance of enhancing the treatment options available for this debilitating disease,” said Neil Solomons, M.D., Aurinia’s Chief Medical Officer. “The speed in which patients achieved CR, which is consistent with our open-label AURION study, is encouraging and we are absolutely delighted by the medical community’s reception to the data. We remain focused on advancing the clinical development program for voclosporin, fulfilling our goal of improving long-term outcomes for patients.”

The AURA study enrolled 265 patients in 20 countries using low (23.7 mg BID), high dose voclosporin (39.5 mg BID) or placebo added to standard of care of mycophenolate mofetil (MMF) and steroids in active LN. The study met its primary endpoint with statistically significant complete remission rates in the 23.7mg BID arm, and demonstrated statistically significant improvements across all secondary endpoints: Partial Remission (PR); time to CR and PR; reduction in Systemic Lupus Erythematosus Disease Activity Index or SLEDAI score; and reduction in UPCR over the 24-week treatment period.

Adverse events were higher in the voclosporin treatment arms versus the control arm, which is consistent with increased immunosuppression. The overall mortality rate was similar to other recent global LN trials; all were considered unrelated to the study drug. The AURA study remains ongoing until its 48-week secondary endpoints, which will be available in Q1 2017.

Based on recent FDA feedback, Aurinia expects to initiate a single Phase III clinical trial of voclosporin 23.7mg BID (AURORA) in Q2 2017. Aurinia believes this Phase III clinical trial whose design is consistent with the ongoing AURA study, will support a New Drug Application (NDA) submission.

### **About AURION**

The AURION study or “Aurinia Early Urinary Protein Reduction Predicts Response Study” is an open-label, exploratory study being conducted in multiple sites in Malaysia to assess the short term predictors of response using voclosporin (23.7mg) in combination with mycophenolate mofetil and oral corticosteroids in patients with active lupus nephritis. This study will examine biomarkers of disease activity at 8 weeks and their ability to predict response at 24 and 48 weeks.

### **About AURORA**

The AURORA study is a 52-week global double-blind placebo controlled phase III study that will compare the efficacy of one dose of voclosporin (23.7mg BID) or placebo added to current standard of care of mycophenolate mofetil (MMF, also known as CellCept®) in achieving renal response (formerly referred to as complete remission) in patients with active

LN. Both arms will also receive low doses of corticosteroids as part of background therapy after a stringent taper.

### ***About Voclosporin***

Voclosporin, an investigational drug, is a novel and potentially best-in-class calcineurin inhibitor (“CNI”) with clinical data in over 2,000 patients across indications. Voclosporin is an immunosuppressant, with a synergistic and dual mechanism of action that has the potential to improve near- and long-term outcomes in LN when added to standard of care (MMF). By inhibiting calcineurin, voclosporin blocks IL-2 expression and T-cell mediated immune responses. It is made by a modification of a single amino acid of the cyclosporine molecule which has shown a more predictable pharmacokinetic and pharmacodynamic relationship, an increase in potency, an altered metabolic profile, and potential for flat dosing. The Company 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.

### ***About Lupus Nephritis (LN)***

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 and affects more than 500,000 people in the United States (mostly women). The disease is highly heterogeneous, affecting a wide range of organs & tissue systems. It is estimated that as many as 60% of all SLE patients have clinical LN requiring treatment. Unlike SLE, LN has straightforward disease outcomes where an early response correlates with long-term outcomes, measured by proteinuria. In patients with LN, renal damage results in proteinuria and/or hematuria and a decrease in renal function as evidenced by reduced estimated glomerular filtration rate (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 is a clinical stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. The Company is currently developing voclosporin, an investigational drug, for the treatment of lupus nephritis (LN). The Company is headquartered in Victoria, BC and focuses its development efforts globally. Visit [www.auriniapharma.com](http://www.auriniapharma.com) for more information.

### ***Forward Looking Statements***

This press release contains forward-looking statements, including statements related to Aurinia's regulatory strategy, Aurinia's analysis, assessment and conclusions of the results of the AURA-LV clinical study, and the efficacy and commercial potential of voclosporin. It is possible that such results or conclusions may change based on further analyses of these data. Words such as "plans," "intends," "may," "will," "believe," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are

based upon Aurinia's current expectations. Forward-looking statements involve risks and uncertainties. Aurinia's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risk that Aurinia's analyses, assessment and conclusions of the results of the AURA-LV clinical study set forth in this release may change based on further analyses of such data, and the risk that Aurinia's clinical studies for voclosporin may not lead to regulatory approval. These and other risk factors are discussed under "Risk Factors" and elsewhere in Aurinia's Annual Information Form for the year ended December 31, 2015 filed with Canadian securities authorities and available at [www.sedar.com](http://www.sedar.com) and on Form 40-F with the U.S. Securities Exchange Commission and available at [www.sec.gov](http://www.sec.gov), each as updated by subsequent filings, including filings on Form 6-K. Aurinia expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Aurinia's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

View source version on businesswire.com:

<http://www.businesswire.com/news/home/20161116005439/en/>

Aurinia Pharmaceuticals Inc.

Celia Economides

Head of IR & Communications

[ceconomides@auriniapharma.com](mailto:ceconomides@auriniapharma.com)

Source: Aurinia Pharmaceuticals Inc.