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# **Aurinia Announces Voclosporin Meets 48-Week Remission Endpoints, Achieving Highest Complete Remission Rate of Any Global Lupus Nephritis Study**

*- Low dose voclosporin achieves CR rate of 49.4% at 48 weeks ( $p < .001$ )*

*- AURORA Phase III trial with low dose voclosporin on track to commence in Q2 2017*

*- Conference call & webcast 8:30am ET tomorrow*

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 announced top-line results from its Phase IIb AURA-LV (AURA) study in lupus nephritis (LN). At 48 weeks, the trial met the complete and partial remission ("CR"/ "PR") endpoints, demonstrating statistically significantly greater CR and PR in patients in both low dose (23.7mg of voclosporin twice daily ( $p < .001$ )) and high dose (39.5mg twice daily ( $p = .026$ )) cohorts versus the control group.

Each arm of the study included the current standard of care of mycophenolate mofetil (MMF) as background therapy and a forced steroid taper to 5mg/day by week 8 and 2.5mg by week 16. No unexpected safety signals were observed and there were no additional deaths in the voclosporin treated patients; however, there were three deaths and one malignancy reported in the control arm after completion of the study treatment period. Additional data analyses for the AURA study at 48 weeks will be released at future corporate, medical and scientific meetings.

"Lupus nephritis (LN) is one of the most severe complications of systemic lupus erythematosus. The current treatments of LN are toxic and the complete renal response rates are unacceptably low. For the last several years the community of lupus researchers in collaboration with the pharmaceutical industry have been engaged in finding more effective therapies for LN, but success has been difficult to achieve," said Brad Rovin, MD, FASN, Director of Nephrology and Vice Chairman of Research for the Department of Internal Medicine at the Ohio State University Wexner Medical Center. "The AURA trial's long-term results convincingly demonstrate that the addition of voclosporin to standard of care treatment is superior to standard of care alone. These data are not only statistically significant, but clinically important. Twice as many patients given 23.7mg voclosporin twice daily achieved a complete renal response compared to those treated with placebo. This is an impressive renal response rate and these results may shift the treatment paradigm of LN. Based on these encouraging data, I am looking forward to the Phase III trial of voclosporin in LN."

The 24 and 48-week top-line efficacy results are summarized below:

Endpoint	Treatment	24 weeks	Odds ratio	P-value*	48 weeks	Odds Ratio	P-value*
Complete Remission	23.7mg VCS BID	33%	2.03	p=.045	49%	3.21	p<.001
	39.5mg VCS BID	27%	1.59	p=.204	40%	2.10	p=.026
	Control Arm	19%	NA	NA	24%	NA	NA
Partial Remission	23.7mg VCS BID	70%	2.33	p=.007	68%	2.34	p=.007
	39.5mg VCS BID	66%	2.03	p=.024	72%	2.68	p=.002
	Control Arm	49%	NA	NA	48%	NA	NA

*\*All p-values are vs control*

“We are grateful to both the patients and investigators who have worked with us on this groundbreaking program. Voclosporin is the first and only treatment candidate that has demonstrated such a clear treatment effect for LN patients,” said Neil Solomons, MD, Aurinia’s Chief Medical Officer. “These data provide us with tremendous confidence that we can execute a successful Phase III program and make a meaningful impact on patients’ lives.”

“Lupus nephritis carries with it life-threatening complications, including kidney failure. The treatment of the disease is challenging, and steroid side-effects are often difficult for patients to endure. The National Kidney Foundation supports the development of steroid-sparing treatment options, and we look forward to following the results of the Phase III trial,” said Joseph Vassalotti, MD, Chief Medical Officer, National Kidney Foundation.

### Conference Call and Webcast Details

Aurinia will host a conference call and webcast tomorrow, March 2, 2017 at 8:30am Eastern Standard Time to provide an overview of the AURA 48-week top-line results. In order to participate in the conference call, please dial +1-877-407-9170 (Toll-free U.S. & Canada). An audio webcast can be accessed under "News/Events" through the "Investors" section of the Aurinia corporate website at [www.auriniapharma.com](http://www.auriniapharma.com). A replay of the webcast will be available on Aurinia’s website.

### About AURA-LV

The AURA–LV study (Aurinia Urinary protein Reduction in Active Lupus with Voclosporin) is a 48-week study comparing the efficacy of two doses of voclosporin added to current standard of care of MMF against standard of care with placebo in achieving CR in patients with active LN. All arms also received low doses of corticosteroids as background therapy. 265 patients were enrolled at centers in 20 countries worldwide. On entry to the study, patients were required to have a diagnosis of LN according to established diagnostic criteria (American College of Rheumatology) and clinical and biopsy features indicative of highly active nephritis. The 24-week primary and secondary endpoints were released in Q3 2016 where the primary and all secondary endpoints were met. CR is a composite endpoint that

includes: confirmed UPCR of  $\leq 0.5$  mg/mg; normal, stable renal function ( $\geq 60$  mL/min/ $1.73\text{m}^2$  or no confirmed decrease from baseline in eGFR of  $\geq 20\%$ ); presence of sustained, low dose steroids ( $\leq 10$ mg prednisone from week 16-24); and no administration of rescue medications. PR in the trial is measured by a  $\geq 50\%$  reduction in UPCR with no concomitant use of rescue medication.

### ***About Voclosporin***

Voclosporin, an investigational drug, is a novel and potentially best-in-class calcineurin inhibitor (“CNI”) with clinical data in over 2,200 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)***

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 LN. The company is headquartered in Victoria, BC and focuses its development efforts globally. [www.auriniapharma.com](http://www.auriniapharma.com)

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

This press release contains forward-looking statements, including statements related to Aurinia’s ability to execute a successful Phase III program and voclosporin potentially shifting the treatment paradigm for LN, Aurinia’s analysis, assessment and conclusions of the results of the AURA-LV clinical study. 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, except as required by law.

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