Aurinia Doses First Patient in AURORA Phase 3 Clinical Trial of Voclosporin in Lupus Nephritis

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 that the first patient has been dosed in AURORA, the Company’s Phase 3 confirmatory clinical trial evaluating voclosporin for the treatment of lupus nephritis (LN), an autoimmune disease caused by lupus that involves extreme inflammation and failure of the kidneys.

“Dosing our first patient today is an important milestone for the Company,” said Neil Solomons, M.D., Chief Medical Officer of Aurinia. “Our Phase 3 trial design is nearly identical to that of our successful Phase 2 AURA trial which demonstrated the potential of voclosporin to increase both speed and rates of remission in patients with active LN. We remain dedicated to advancing this treatment and making a meaningful impact in the lives of patients suffering from LN and those around them.”

AURORA is a 52-week global double-blind placebo controlled study, designed to demonstrate that voclosporin added to the current standard of care of mycophenolate mofetil (MMF) can increase overall renal response rates in the presence of extremely low steroids. The primary endpoint is complete renal response at 52 weeks. This trial will recruit ~320 patients and is intended to support full marketing approval of voclosporin for patients with LN across multiple regulatory jurisdictions.

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“Lupus nephritis is a devastating disease which if not managed, can be life-threatening. There is no approved medication to treat the condition which mostly affects women in their childbearing years,” said Mary Anne Dooley, M.D., M.P.H., Adjunct Professor of Medicine at University of North Carolina School of Medicine and principal investigator for the study. “The AURA Phase II results showed great promise and if replicated in Phase 3, voclosporin has the potential to change the current treatment paradigm for LN.”

About AURORA
The AURORA study is a 52-week global double-blind placebo controlled Phase 3 study that will compare the efficacy of one dose of voclosporin (23.7mg BID) to placebo when 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. For further questions on the trial or interest in
participating, please see our website (http://www.auriniapharma.com/for-patients-physicians/clinical-trials) or contact us at clinicaltrials@auriniapharma.com.

**About Voclosporin**
Voclosporin, an investigational drug, is a novel and potentially best-in-class calcineurin inhibitor (“CNI”) with clinical trial 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. Voclosporin is made by a modification of a single amino acid of the cyclosporine molecule which results in a more predictable pharmacokinetic and pharmacodynamic relationship with potential for flat dosing. In addition, Voclosporin is more potent than and has an improved metabolic profile versus cyclosporine. 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, an inflammation of the kidney caused by Systemic Lupus Erythematosus (“SLE”), represents a serious progression of SLE. SLE is a chronic, complex and often disabling disorder that 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 a strong surrogate marker, proteinuria, which correlates with meaningful longer term clinical outcome. 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. 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, 2016 filed with Canadian securities authorities and available at www.sedar.com and on Form 40-F with the U.S. Securities Exchange Commission and available at 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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Aurinia Pharmaceuticals Inc.
Investor Contact:
Celia Economides
VP, Public Affairs
ceeconomides@auriniapharma.com

or

Media Contact:
Christopher Hippolyte, 212-364-0458
Christopher.hippolyte@inventivhealth.com

Source: Aurinia Pharmaceuticals Inc.