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# Aurinia Announces Preliminary Topline Data From its Open Label Aurion Study in Lupus Nephritis

***100% of Patients receiving multi-target therapy with voclosporin achieved at least a 25% reduction of proteinuria at 8 weeks with a mean decrease of 72%***

VICTORIA, British Columbia-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH / TSX:AUP) ("Aurinia" or the "Company") announced today that it has completed a preliminary analysis of its AURION (Aurinia early Urinary protein Reduction Predicts Response) study. In the first seven patients that have reached at least eight weeks of therapy in the AURION study, 100% (7/7) have achieved at least a 25% reduction in proteinuria compared to study entry. A 25% reduction in proteinuria has been shown to be predictive of a positive clinical response at 24 weeks<sup>1</sup>. All of the other pre-specified eight week biomarkers of active lupus nephritis (LN) have also improved and are trending towards normalization. These biomarkers have also been shown to be predictive of a positive clinical response at 24 weeks<sup>1</sup>.

In the first eight weeks of a 48 week regimen of multi-target therapy including voclosporin in AURION, an overall mean reduction of proteinuria of 72% compared to pre-treatment levels was observed, and 57% (4/7) of these patients achieved complete remission as defined by a urinary protein creatinine ratio of  $\leq 0.5\text{mg/mg}$ . Overall renal function as measured by eGFR in these patients has remained stable.

The AURION study is an open label, single arm, exploratory study assessing the ability of biomarkers at 8 weeks to predict clinical response rates at 24 and 48 weeks in subjects taking voclosporin 23.7mg twice daily in combination with standard of care, mycophenolate mofetil and corticosteroids, in patients with active LN.

"We are encouraged by these results. This is the first time voclosporin has been used in this particular patient population." said Dr. Neil Solomons, MD, Chief Medical Officer of Aurinia Pharmaceuticals Inc. "It appears that this data supports our hypothesis that utilizing a multi-targeted approach to treating LN with voclosporin can help patients suffering from this disease. We are very excited to see the results from the 265 patient AURA study later this year."

The Company will continue to review the AURION data and release more information as it becomes available, a webcast has been scheduled for Tuesday February 16<sup>th</sup>, 2016 at 4:30pm Eastern Standard Time. Interested parties can join the webcast at the specified time at the following URL: <http://public.viavid.com/index.php?id=118297>

<sup>1</sup>Dall'Era, M., Stone, D., Levesque, V., Cisternas, M., & Wofsy, D. (2011). *Arthritis Care and Research*, 63(3), 351–357.

## **About Aurinia**

Aurinia is a clinical stage pharmaceutical company focused on the global nephrology market. The fully-enrolled Phase 2b AURA-LV clinical trial is evaluating the efficacy of its lead drug, voclosporin, as a treatment for active LN. LN is an inflammation of the kidneys, that if inadequately treated can lead to end-stage renal disease, making LN a serious and potentially life-threatening condition.

Voclosporin is a novel and potentially best-in-class calcineurin inhibitor (“CNI”) with extensive clinical data in over 2,000 patients in other indications. Voclosporin is made by a modification of a single amino acid of the cyclosporine molecule (a CNI approved for use in transplant patients since 1983). This modification results in a more predictable pharmacokinetic and pharmacodynamic relationship, an increase in potency vs. cyclosporine, an altered metabolic profile, and potential for flat dosing.

## **About AURA:**

The AURA–LV study or “Aurinia Urine Protein Reduction in Active Lupus Nephritis Study” is an adequate and well-controlled clinical trial that enrolled 265 patients and is being conducted in over 20 countries worldwide. This trial will compare the efficacy of voclosporin against placebo in achieving remission in patients with active lupus nephritis. The AURA-LV study is designed to demonstrate that voclosporin can induce a rapid and sustained reduction of proteinuria in the presence of extremely low steroid exposure. It will compare two dosage groups of voclosporin (23.7mg and 39.5mg) compared to placebo, with all patients receiving mycophenolate mofetil (MMF) and oral corticosteroids as background therapy. There will be a primary analysis to determine complete remission at week 24 (confirmed at 26 weeks) and various secondary analyses at week 48 which include biomarkers and markers of non-renal SLE.

## **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.

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