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Aurinia Announces Development Plans for Voclosporin in Europe and Japan

- Single Phase III trial (AURORA) to serve as basis for regulatory submissions in major markets—US, Europe, and Japan

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH / TSX:AUP) (“Aurinia” or the “Company”), today announced the outcome of discussions with both the European Medicines Agency (EMA) and the Pharmaceutical and Medical Devices Agency (PMDA) in Japan regarding the development of voclosporin for the treatment of active lupus nephritis (LN). Pursuant to these discussions, the Company believes that the confirmatory data that can be generated from the single Phase III clinical trial (AURORA) and the recently completed AURA-LV (AURA) Phase IIb study should support regulatory submissions in the US, Europe and Japan.

“Our interactions with regulators in all three jurisdictions have given us a clear pathway for Phase III, and we are confident in our ability to execute AURORA successfully based on their feedback and the information gleaned from the AURA study,” said Lawrence D. Mandt, Vice President of Quality and Regulatory Affairs at Aurinia. “The productive conclusion of these regulatory interactions marks a milestone in our development program and brings this exciting new therapeutic option one step closer to those patients suffering from LN.”

The Phase III AURORA trial will be a global 52-week double-blind, placebo controlled study of approximately 320 patients. Patients will be randomized 1:1: to either of 23.7mg voclosporin BID and mycophenolate mofetil (MMF) or MMF and placebo, with both arms receiving a stringent oral corticosteroid taper. As in AURA, the study population will be comprised of patients with biopsy-proven active LN who will be evaluated on the primary efficacy endpoint of complete remission, or renal response, at 52 weeks, a composite which includes:

- Urinary/protein creatinine ratio (UPCR) of ≤0.5mg/mg
- Normal, stable renal function (≥60 mL/min/1.73m^2 or no confirmed decrease from baseline in eGFR of >20%)
- Presence of sustained, low dose steroids (≤10mg prednisone from week 16-24)
- No administration of rescue medications

“Based on the recent learnings from the positive AURA study at 48 weeks, we intend to use a UPCR of ≤0.5mg/mg and evaluate the primary endpoint at 52 weeks in AURORA,” added Richard M. Glickman, Aurinia’s Chief Executive Officer. “We are on track to initiating the global AURORA study this quarter and fulfilling our goal of improving the long-term outcomes for patients with this disease.”

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 AURA-LV
The AURA–LV study (Aurinia Urinary Protein Reduction in Active Lupus with Voclosporin) was 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 complete remission (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 with top-line 48-week results announced in Q1 2017. The 48-week data has been accepted for a late-breaking presentation at National Kidney Foundation (NKF) Spring Clinical Meeting taking place April 18-22 in Orlando, FL.

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 in 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.

Forward Looking Statements
This press release contains forward-looking statements, including statements around Aurinia's global development and regulatory strategy, analysis, assessment and conclusions around the future development 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 future development and commercial potential of voclosporin 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.

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