November 2, 2016

Aurinia Announces Plans for Single Phase III Clinical Trial for Voclosporin in the Treatment of Lupus Nephritis Following Successful Completion of End of Phase II Meeting With FDA

-Voclosporin 23.7mg BID to advance into double-blind placebo controlled Phase III study

-AURORA Phase III study design consistent with AURA

-Trial expected to commence in Q2 2017

-Conference Call and webcast at 8:30am ET tomorrow

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH) (TSX:AUP) ("Aurinia" or the "Company"), today announced its plans for a single Phase III clinical trial for voclosporin in the treatment of lupus nephritis (LN). Pursuant to its recent End of Phase II meeting with the U.S. Food & Drug Administration (FDA) Division of Pulmonary, Allergy and Rheumatology Products, Aurinia believes this Phase III clinical trial whose design is consistent with the ongoing AURA study, will support a New Drug Application (NDA) submission.

"We are thrilled with the outcome and direction received from the FDA. With a clear path forward for voclosporin's development to treat LN, we are mobilizing quickly to initiate the Phase III study in Q2 next year, fulfilling our goal of improving the long-term outcomes for patients with this disease," added Charles Rowland, Aurinia's Chief Executive Officer.

The Phase III AURORA trial will be a global 52-week double-blind, placebo controlled study of approximately 320 patients. The Company is finalizing the study protocol and regulatory submissions and in parallel is working on site selection with trial initiation anticipated in Q2 2017. Patients will be randomized 1:1: to either of 23.7mg voclosporin BID and MMF or MMF and placebo, with both arms receiving a stringent oral corticosteroid taper. The study population will be comprised of patients with biopsy-proven active LN who will be evaluated on the primary efficacy endpoint of renal response at 24 weeks, a composite which includes:

- Urinary/protein creatinine ratio (UPCR) of ≤0.7mg/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

The readout of the primary endpoint of renal response at 24 weeks will occur after database lock at 52 weeks at which point the Company intends to submit an NDA. Patients completing the 52-week study will then have the option to roll-over into a 104 week blinded continuation study. These data will allow the Company to assess long-term outcomes in LN patients that will be valuable in a post-marketing setting in addition to future interactions with various regulatory authorities.

While voclosporin has received fast track designation, the FDA has informed the Company that voclosporin is not eligible for breakthrough therapy designation at this time. Aurinia will continue to benefit from its fast track designation which includes more frequent communications with the FDA and potential for priority review and an option to submit a rolling NDA submission, which may expedite the review process.

"We have shared a substantial amount of efficacy and safety data with the FDA and are confident in our ability to execute a successful Phase III clinical trial 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. "We remain committed to addressing the unmet needs of patients living with LN, a devastating disease, and look forward to making this product available to patients as soon as possible."

Conference Call and Webcast Details
Aurinia will host a conference call and webcast tomorrow, November 3, 2016 at 8:30a.m. Eastern Daylight Time to provide a clinical and regulatory update on voclosporin. In order to participate in the conference call, please dial +1-877-407-9170 (Toll-free US & Canada). An audio webcast can be accessed under "Webcasts" through the "Investors" section of the Aurinia corporate website at www.auriniapharma.com. A replay of the webcast will be available on Aurinia's website for 45 days.

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) 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 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 48-week results to be announced in Q1 2017. The 24-week data have been accepted for late-breaking presentations at the American College of Rheumatology (ACR) and American Society of Nephrology (ASN).

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 in other 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) 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 measures 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, 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. Canada and focuses its development efforts globally. www.auriniapharma.com.

Forward Looking Statements

This press release contains forward-looking statements, including statements around Aurinia's analysis, assessment and conclusions around the future development and commercial potential of voclosporin; the benefits of FDA fast track designation and the timing of future clinical trials. 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, 2015 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.

View source version on businesswire.com:
http://www.businesswire.com/news/home/20161102006768/en/

Aurinia Pharmaceuticals
Celia Economides
Head of IR & Communications
ceconomides@auriniapharma.com

Source: Aurinia Pharmaceuticals