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Aurinia Initiates First Clinical Study of Voclosporin for Japan

Study has potential to reduce Japanese development timelines

VICTORIA, British Columbia-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH / TSX:AUP) (“Aurinia” or the “Company”) announced today that after constructive interactions with the Japanese Pharmaceuticals and Medical Devices Agency (“PMDA”), the Company will initiate a study of voclosporin in healthy Japanese volunteers. With positive results from the pending Phase 2b AURA-LV study in lupus nephritis ("LN") and supportive safety, tolerability, pharmacokinetic and pharmacodynamic data from this clinical study, the Company hopes to be able to incorporate Japanese patients into future global voclosporin studies, eliminating the need to conduct a stand-alone Japanese trial.

“Japan represents a substantial market opportunity for the Company” said Charlie Rowland, CEO of Aurinia Pharmaceuticals Inc. “This Japanese study has the potential to reduce development timelines for voclosporin in this major market. With voclosporin’s product attributes, we’re confident that we may be able to offer Japanese patients suffering from LN a more suitable treatment approach compared to the current therapies.”

“Our interactions with the PMDA to date have been beneficial” stated Lawrence Mandt, Vice President of Regulatory and Quality for the Company. “We’re looking forward to continued productive discussions in order to bring voclosporin to Japanese LN patients as quickly as is practical.”

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.

About voclosporin

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.

We seek Safe Harbor.

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