



Aurinia Presents Integrated Time to Renal Response Data from the AURA-LV and AURORA Trials, along with Voclosporin Drug-Drug Interaction Data at ACR Convergence 2020

- *Integrated analysis confirms addition of voclosporin to standard-of-care resulted in faster Renal Response compared to standard-of-care alone in lupus nephritis -*
- *DDI study demonstrates no clinically meaningful interaction between voclosporin and MMF, supporting differentiation as a potential best-in-class CNI -*

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (Nasdaq: AUPH / TSX:AUP) (Aurinia or the Company), a late-stage clinical biopharmaceutical company, today announced data from an integrated analysis of the AURA-LV and AURORA pivotal trials that further supports voclosporin as a potential treatment for lupus nephritis (LN) in a presentation at the American College of Rheumatology (ACR) Convergence 2020. The Company also shared data from a clinical drug-drug interaction (DDI) study in patients with systemic lupus erythematosus (SLE), showing that voclosporin does not have a meaningful drug-drug interaction when administered with mycophenolate mofetil (MMF). The topline results from this DDI study were previously [announced](#) in late 2019.

The data at ACR were presented by Ellen Ginzler, M.D., MPH, Distinguished Teaching Professor of Medicine and Chief of Rheumatology at the SUNY Downstate Health Sciences University and Teun van Gelder, M.D., Ph.D., Professor in Clinical Pharmacology for the Department of Clinical Pharmacy and Toxicology at the Leiden University Medical Center.

“We are delighted to share more encouraging data on the use of voclosporin for lupus nephritis to this influential group of rheumatology experts at ACR,” said Neil Solomons, M.D., Chief Medical Officer of Aurinia. “With few effective options, rheumatologists have struggled to find effective therapies for patients with lupus nephritis. These two studies, along with the growing body of data supporting the use of voclosporin, clearly demonstrate the benefits of this therapy to provide effective and safe treatment.”

The integrated data presented by Dr. Ginzler demonstrated that patients with LN treated with voclosporin in combination with MMF and low-dose steroids achieved statistically superior and faster Renal Response (RR) rates compared to patients treated with MMF and steroids alone. Treatment with voclosporin (VCS) resulted in clinically meaningful and a statistically significant higher RR rate of 43.7% compared to 23.3% in the control arm at one year (OR 2.76, 95% CI: 1.88, 4.05; $p < 0.0001$) and at six months (VCS 31.7%; placebo 20.3%), [OR: 2.01; 95% CI: 1.34, 3.01; $p=0.0008$]. Furthermore, a 50% reduction in urine protein/creatinine

ratio (UPCR) from baseline at any time was achieved by 93.7% of patients treated with voclosporin compared with 75.2% of patients receiving placebo, with a median time to 50% reduction in UPCR of 29 days versus 58 days, respectively. The time taken to reach a 50% reduction in UPCR was significantly shorter for the voclosporin group than the placebo group (HR 1.96; 95% CI: 1.61, 2.38; $p < 0.0001$). At one year, 160 (75.8%) patients in the voclosporin arm and 150 (73.9%) patients in the placebo arm were on oral prednisone ≤ 2.5 mg /d.

The AURA-LV and AURORA studies were of similar design and conducted in comparable patient populations. The data from both studies for patients treated with the recommended voclosporin dose of 23.7 mg BID (AURORA; n=179, AURA; n=89) or with matching placebo (AURORA; n= 179, AURA-LV; n=89) were therefore pooled for an integrated analysis of efficacy.

Dr. Van Gelder presented data from a clinical DDI study in patients with SLE that investigated the potential effect of voclosporin on blood levels of mycophenolate acid (MPA), the active moiety MMF. MMF, also known as CellCept®, is considered by treating physicians to be part of the current standard of care for LN in the United States. The study demonstrated for the first time that voclosporin does not have a meaningful drug-drug interaction when administered with MMF. In contrast to cyclosporine A, voclosporin does not have clinically significant impacts on MPA blood concentrations, which indicates that voclosporin and MMF can be administered concomitantly without the need to adjust the dose of MMF.

These data presented at ACR Convergence 2020 were submitted as part of voclosporin's new drug application (NDA) to the United States Food and Drug Administration (FDA). The FDA accepted the NDA and has assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 22, 2021.

About Aurinia

Aurinia Pharmaceuticals is a late-stage clinical biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are impacted by serious diseases with a high unmet medical need. The Company is currently seeking FDA approval of voclosporin for the potential treatment of LN. The Company's head office is in Victoria, British Columbia and its U.S. commercial hub is in Rockville, Maryland. The Company focuses its development efforts globally.

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