

December 4, 2019



Aurinia Announces Positive AURORA Phase 3 Trial Results Demonstrating Voclosporin Superiority Over Standard of Care in Lupus Nephritis

- *Voclosporin achieved statistically superior Renal Response rate ($p < 0.001$) and comparable safety profile versus standard of care -*
- *Statistically significant results demonstrated in all pre-specified hierarchical secondary endpoints -*
- *Aurinia plans to file an NDA submission to the FDA during the first half of 2020 -*
- *Company to host conference call to discuss results at 8:30 a.m. ET on Thursday, December 5, 2019 -*

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX:AUP) ("Aurinia" or the "Company"), a late-stage clinical biopharmaceutical company focused on advancing voclosporin across multiple inflammatory and autoimmune conditions, today announced positive efficacy and safety results from its pivotal AURORA Phase 3 trial of voclosporin, in combination with mycophenolate ("MMF") and low-dose corticosteroids, in the treatment of lupus nephritis ("LN").

"This extraordinary pivotal data confirms voclosporin's ability to achieve statistically significant improvements in clinically meaningful endpoints for this complex disease, with a comparable safety profile to the current standard of care," said Neil Solomons, M.D., Chief Medical Officer of Aurinia. "This data represents a significant advance for people living with LN, which can lead to irreversible kidney damage, eventual kidney failure and death."

This global study in which 357 patients with active LN were enrolled, met its primary endpoint of Renal Response rates of 40.8% for voclosporin vs. 22.5% for the control (OR 2.65; $p < 0.001$). Additionally, all pre-specified hierarchical secondary endpoints achieved statistical significance in favor of voclosporin, which included Renal Response at 24 weeks, Partial Renal Response at 24 and 52 weeks, time to achieve urinary protein-to-creatinine ratio ("UPCR") ≤ 0.5 , and time to 50% reduction in UPCR. The robustness of the data was also supported by all pre-specified subgroup analyses (age, sex, race, biopsy class, region, and prior MMF use) favoring voclosporin.

	Measure	Result	Odds Ratio [95% CI]	p-value
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Primary Endpoint	Renal Response at 52 weeks	Voclosporin 40.8% Control 22.5%	2.65 [1.64, 4.27]	p < 0.001
Secondary Endpoints	Renal Response at 24 weeks	Voclosporin 32.4% Control 19.7%	2.23 [1.34, 3.72]	p = 0.002
	Partial Renal Response at 24 weeks	Voclosporin 70.4% Control 50.0%	2.43 [1.56, 3.79]	p < 0.001
	Partial Renal Response at 52 weeks	Voclosporin 69.8% Control 51.7%	2.26 [1.45, 3.51]	p < 0.001
	Time to UPCR \leq 0.5	Voclosporin faster than Control	2.02 [1.51, 2.70] Hazard Ratio	p < 0.001
	Time to 50% reduction in UPCR	Voclosporin faster than Control	2.05 [1.62, 2.60] Hazard Ratio	p < 0.001

Voclosporin was well tolerated with no unexpected safety signals. Serious adverse events (“SAEs”) were reported in 20.8% of voclosporin patients vs. 21.3% in the control arm. Infection was the most commonly reported SAE with 10.1% of voclosporin patients versus 11.2% of patients in the control arm. Overall mortality in the trial was low, with six deaths observed; one in the voclosporin arm and five in the control group. Additionally, the voclosporin arm showed no significant decrease at week 52 in estimated glomerular filtration rate (“eGFR”) or increase in blood pressure, lipids or glucose, which are common adverse events associated with legacy calcineurin inhibitors (“CNIs”).

“These data represent a potential game changer for patients suffering from this debilitating disease,” commented Brad Rovin, MD, FASN, Chief, Division of Nephrology and Medical Director of the Clinical Trials Management Organization at the Ohio State University Wexner Medical Center. “This confirmatory Phase 3 result represents a clinically meaningful leap forward in the treatment of lupus nephritis. Importantly, the data indicate no excess of adverse events in the voclosporin group compared to patients managed with standard of care alone.”

Voclosporin was granted Fast Track designation by the FDA in 2016. Aurinia plans to submit an NDA to the FDA in the first half of 2020.

“We are thrilled with the outcomes reported today from the AURORA trial, which unequivocally demonstrate the tremendous potential for voclosporin to play an important role in the treatment of the approximately one million people worldwide living with LN,” said Peter Greenleaf, President and Chief Executive Officer of Aurinia. “We are aware of the intense need for a clinically impactful therapy for this serious disease and are working with urgency to complete regulatory filings in the U.S. and worldwide. If approved, we look forward to potentially making voclosporin available to patients beginning in 2021.”

“The treatment of lupus nephritis has been extremely challenging to date, and people with lupus are in need of innovative treatments for this serious disease. We’re proud to have been part of this important achievement through our work educating people with lupus nephritis about the trial and the importance of clinical trial participation,” said Stevan W. Gibson, President and Chief Executive Officer, Lupus Foundation of America. “Voclosporin is the first novel treatment that has demonstrated therapeutic efficacy for people living with lupus nephritis and today marks an important advance in the treatment of this potentially life-threatening disease.”

Aurinia expects to present further data from this trial at a future scientific conference in 2020.

Aurinia will host a conference call and webcast to discuss these results tomorrow, Thursday, December 5, 2019 at 8:30 a.m. ET. This event can be accessed on the investor section of the Aurinia website at www.auriniapharma.com.

About AURORA

The AURORA clinical trial is a global, double-blind, placebo-controlled study to evaluate whether voclosporin when added to background therapy of mycophenolate mofetil (MMF)/CellCept® can increase speed of and overall renal response rates in the presence of low dose steroids. The primary endpoint for the study is complete renal response at 52 weeks, after which patients can choose to enroll into a 104-week blinded extension study.

Renal response was defined as UCPR of ≤ 0.5 mg/mg, eGFR ≥ 60 mL/min/1.73 m², or no confirmed decrease from baseline in eGFR of $> 20\%$, presence of sustained, low dose steroids and no administration of rescue medication. The target enrollment of 324 patients was surpassed with a total of 357 lupus nephritis (LN) patients randomized globally across sites in 27 countries.

About AURORA 2 Extension

Eligible patients completing the AURORA trial had the option to roll over into a 104-week blinded extension study (the "AURORA 2 extension study"). A total of 216 patients enrolled into the AURORA 2 extension study. The data from the AURORA 2 extension study will allow the company to assess the long-term benefit/risk of voclosporin in LN patients, however, this study is not a requirement for potential regulatory approval for voclosporin. Data from the AURORA 2 extension study assessing long-term outcomes in LN patients should be valuable in a post-marketing setting and for future interactions with various regulatory authorities.

About Voclosporin

Voclosporin, an investigational drug, is a novel and potentially best-in-class calcineurin inhibitor (“CNI”) with clinical data in over 2,600 patients across indications. Voclosporin is an immunosuppressant, with a synergistic and dual mechanism of action. By inhibiting calcineurin, voclosporin blocks IL-2 expression and T-cell mediated immune responses and stabilizes the podocyte in the kidney. It has been shown to have a more predictable pharmacokinetic and pharmacodynamic relationship (potentially requires no therapeutic drug monitoring), an increase in potency (versus cyclosporine A), and an improved metabolic profile compared to legacy CNIs. Aurinia 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 and until April 2028 with anticipated pediatric extension. Further, a U.S. patent has also been issued covering the voclosporin dosing protocol with a term extending to December 2037, if the FDA incorporates the dosing protocol used in both the AURA and AURORA trials into the product label.

About Lupus Nephritis

Lupus nephritis (“LN”) is 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. The disease is highly heterogeneous, affecting a wide range of organs and tissue systems. Unlike SLE, LN has straightforward disease outcomes (measuring proteinuria) where an early response correlates with long-term outcomes. In patients with LN, renal damage results in proteinuria and/or hematuria and a decrease in renal function as evidenced by reduced 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 Pharmaceuticals is a late clinical-stage 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 developing an investigational drug, for the treatment of lupus nephritis, focal segmental glomerulosclerosis and dry eye syndrome. The Company’s head office is in Victoria, British Columbia and focuses its development efforts globally. For further information, see our website at www.auriniapharma.com.

Forward-Looking Statements

Certain statements made in this press release may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include but are not limited to statements or information with respect to: completing NDA priority review submissions in a successful and timely manner including the anticipated NDA filing during the first half of 2020; the potential for commercial launch of voclosporin for use in LN in 2021; voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity; Aurinia's anticipation that upon regulatory approval, patent protection for voclosporin composition of matter 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 and until April 2028 with anticipated pediatric extension; a US patent has also been issued covering the voclosporin dosing protocol with a term extending to December 2037, if the FDA incorporates the dosing protocol used in both the AURA and the AURORA studies into the product label; that the results of the AURORA clinical study are pivotal and a potential game changer for LN patients; that voclosporin may be positioned to become the standard of care for people living with LN; that Aurinia will present AURORA study results at a future scientific conference during 2020. It is possible that such results or conclusions may change based on further analyses of these data. Words such as "anticipate", "will", "believe", "estimate", "expect", "intend", "target", "plan", "goals", "objectives", "may" and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: the market value for the LN, DES and FSGS programs; that another company will not create a substantial competitive product for Aurinia's LN, DES and FSGS business without violating Aurinia's intellectual property rights; the burn rate of Aurinia's cash for operations; the costs and expenses associated with Aurinia's clinical trials; the planned studies achieving positive results; Aurinia being able to extend and protect its patents on terms acceptable to Aurinia; and the size of the LN, DES or FSGS markets; Aurinia will be able to obtain all necessary regulatory approvals for commercialization of voclosporin for use in LN on terms that are acceptable to it and that are commercially viable; and that Aurinia's intellectual property rights are valid and do not infringe the intellectual property rights of other parties. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

Forward-looking information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following: difficulties, delays, or failures we may experience in the conduct of our clinical trial; difficulties we may experience in completing the development and commercialization of voclosporin; the market for the LN, DES and FSGS business may not be as estimated; Aurinia may have to pay unanticipated expenses; estimated costs for clinical trials may be underestimated, resulting in Aurinia having to make additional expenditures to achieve its current goals; Aurinia not being able to extend or fully protect its

patent portfolio for voclosporin; competitors may arise with similar products; Aurinia may not be able to obtain necessary regulatory approvals for commercialization of voclosporin in a timely fashion, or at all; and Aurinia may not be able to obtain sufficient supply to meet commercial demand for voclosporin in a timely fashion. Although we have attempted to identify factors that would cause actual actions, events or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond our control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information.

Except as required by law, Aurinia will not update forward-looking information. All forward-looking information contained in this press release is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business can be found in Aurinia's most recent Annual Information Form available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at www.sedar.com or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at www.sec.gov/edgar.

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