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Aurinia Completes Submission of New Drug Application to the U.S. Food & Drug Administration for Voclosporin for the Treatment of Lupus Nephritis

- Potential for voclosporin to become the first FDA-approved therapy for the treatment of lupus nephritis -

- NDA Application supported by extensive global clinical program including the pivotal Phase 3 AURORA study and the pivotal Phase 2 AURA LV study -

VICTORIA, British Columbia & ROCKVILLE, Md.--(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 indications, today announced the completion of the rolling submission of a New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") for voclosporin as a potential treatment for lupus nephritis ("LN"), a serious inflammation of the kidneys caused by the autoimmune disease systemic lupus erythematosus ("SLE"). There are currently no FDA-approved treatments for LN. The NDA submission includes a request for Priority Review, which, if granted, would shorten the FDA's review of the NDA to eight months from the time of submission, versus a standard review timeline of 12 months.

"LN is a severe and debilitating consequence of lupus, which can severely impact the quality of life of individuals struggling with this disease. The Aurinia team continues to work incredibly hard towards delivering the first FDA-approved treatment option for those affected by LN in the hope of changing the course of this disease," said Peter Greenleaf, President and Chief Executive Officer of Aurinia. "Our extensive clinical program, including results from both the AURA and AURORA trials, provides strong support for the profile of voclosporin as a novel treatment for lupus nephritis, and we are rapidly advancing our U.S. commercial strategy and infrastructure to support a potential launch early next year."

Lawrence Mandt, Senior Vice President of Quality and Regulatory Affairs, at Aurinia commented, "The excellent Phase 3 clinical results enabled the highly experienced Aurinia team to produce and submit a quality submission for voclosporin ahead of our projections. We now look forward to further dialogue in the coming months with the agency regarding acceptance of the filing and priority review, and a potential approval date in early 2021."

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, where an early reduction in proteinuria correlates with positive 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-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 developing the investigational drug voclosporin for the treatment of lupus nephritis, other proteinuric diseases and dry eye syndrome. The Company's head office is in Victoria, British Columbia, its U.S. commercial hub in Rockville, Maryland, and focuses its development efforts globally.

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: positive efficacy and safety results from the AURORA Phase 3 pivotal trial, including public presentations stating Voclosporin as having Statistical Superiority Over Standard of Care in Lupus Nephritis; completing NDA rolling submissions and filings in a quality, successful and timely manner; having the FDA accept the filing and grant Priority Review, shortening the review time to 8 months instead of 12; the potential for commercial launch of voclosporin for use in LN in 2021; efforts towards delivering the first FDA-approved treatment option for those affected by LN in the hope of changing the course of this disease; timeline challenges due to the COVID-19 outbreak; 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 and DES programs; that another company will not create a substantial competitive product for Aurinia's LN and DES 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 proteinuric kidney disease 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 other proteinuric kidney disease 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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