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Aurinia Receives Notice of Allowance from the US Patent and Trademark Office for Claims Directed to Its Novel Voclosporin Dosing Protocol for Lupus Nephritis

- *Allowed claims cover an individualized flat-dosed pharmacodynamic treatment protocol utilized in the AURA-LV study and the ongoing AURORA study in lupus nephritis*
- *Claims have the potential to protect voclosporin's method of use and dosing protocol for LN until December 2037*

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH/ TSX:AUP) (the "Company" or "Aurinia"), a clinical stage biopharmaceutical company focused on the global immunology market, today announced that it has received a Notice of Allowance from the United States Patent and Trademark Office ("USPTO") for U.S. patent application 15/835,219, entitled "PROTOCOL FOR TREATMENT OF LUPUS NEPHRITIS". The allowed claims broadly cover the novel voclosporin dosing protocol adhered to and required in both the previously reported Phase II AURA-LV study and the ongoing Phase III confirmatory AURORA study. Notably, the allowed claims cover a method of modifying the dose of voclosporin in patients with lupus nephritis (LN) based on patient specific pharmacodynamic parameters.

This Notice of Allowance concludes a substantive examination of the patent application at the USPTO, and after administrative processes are completed and fees are paid, is expected to result in the issuance of a U.S. patent with a term extending to December 2037. Issuance of the patent will expand the scope of intellectual property protection for voclosporin, which already includes robust manufacturing, formulation, synthesis and composition of matter patents.

The Company has also filed for protection of this subject matter under the Patent Cooperation Treaty (PCT) and has the option of applying for similar protection in the member countries thereof. This may lead to the granting of corresponding claims in the treaty countries which include all the major global pharmaceutical markets. "These method of use claims allowed in the U.S. broadly cover the personalized voclosporin dosing protocol utilized across our LN program, which includes specific dose modification requirements that we anticipate being incorporated into any potential future label for

voclosporin in LN,” said Michael R. Martin, Chief Operating Officer of Aurinia.

“This Notice of Allowance is a significant milestone for Aurinia as it enhances our current intellectual property portfolio and provides potential exclusivity for Aurinia’s protocol for the treatment of proteinuric kidney diseases, including LN, until late 2037. Importantly, these claims provide validation of some unique and differentiating features of voclosporin compared to the legacy CNIs.” stated Richard M. Glickman, Chairman and CEO of Aurinia. “Establishing a robust exclusivity platform is a critical part of our strategy as we work towards regulatory approvals in the United States and internationally.”

About Aurinia

Aurinia Pharmaceuticals Inc. 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 potential treatment of lupus nephritis (LN), focal segmental glomerulosclerosis (FSGS), and dry eye syndrome (DES). The company is headquartered in Victoria, British Columbia and focuses its development efforts globally. For further information, see our website at www.auriniapharma.com.

About Voclosporin

Voclosporin, an investigational drug, is a novel and potentially best-in-class CNI with clinical data in over 2,400 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 (vs cyclosporin), and an improved metabolic profile compared to legacy CNIs. Aurinia anticipates that upon regulatory approval, patent protection for voclosporin’s 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. Voclosporin’s unique dosing protocol used in both the AURA-LV and the AURORA studies for LN has also been granted a Notice of Allowance from the USPTO, these allowed claims have the potential to provide additional coverage for voclosporin until late 2037.

About Lupus Nephritis (LN)

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 & 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 estimated glomerular filtration rate (“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.

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: the USPTO granting a new patent for the Company’s protocol with LN; the new patent having a patent term extending to 2037; Aurinia’s new patent claims being listed in the FDA’s Orange book; filings with the PCT leading to the granting of corresponding claims in treaty countries; voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity; the patent life for Aurinia’s patents; and the potential to extend that patent life on the occurrence of certain events. 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: that another company will not create a substantial competitive product without violating Aurinia’s intellectual property rights; that the FDA will grant Aurinia approval for use of voclosporin with LN; that voclosporin in LN would qualify for publication in the FDA’s Orange Book; that the USPTO will issue a new patent once applicable steps have been followed and fees paid in respect of the Notice of Allowance; and Aurinia being able to extend its patents on terms acceptable to Aurinia. 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 AURORA clinical trial; the FDA may not approve voclosporin for use with LN or for any other purpose; Aurinia not being able to extend or protect its patent portfolio for voclosporin or VOS; and competitors may arise with similar or more competitive products. 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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