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Aurinia Announces U.S. Food and Drug Administration Acceptance of the Filing of New Drug Application and Priority Review for Voclosporin for the Treatment of Lupus Nephritis

- FDA grants Priority Review and sets PDUFA date of January 22, 2021 -

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 that the U.S. Food and Drug Administration (FDA) has accepted the filing of its New Drug Application (NDA) 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). The FDA has granted Priority Review for the NDA, which provides an expedited six month review, and has assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 22, 2021. The FDA has also informed the Company that they are not currently planning to hold an advisory committee meeting to discuss the application. The FDA has the option to change this decision based on review of the pending NDA.

“People living with LN are in need of an advanced therapy that quickly drives the disease into remission and mediates kidney damage,” said Peter Greenleaf, President and Chief Executive Officer of Aurinia. “We will continue to collaborate with the FDA during their review process and in parallel build our commercial readiness for a potential approval and commercial launch in the first quarter of 2021.”

Priority review is granted to therapies that the FDA determines have the potential to provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition. Under PDUFA, a Priority Review targets a review time of six months compared to a standard review time of 10 months. Voclosporin was also granted Fast Track designation by the FDA in 2016.

The NDA for voclosporin is supported by data from a substantial global clinical program including two pivotal studies, Phase 3 AURORA and Phase 2 AURA-LV. Additional AURORA study data was recently presented at the EULAR and ERA-EDTA virtual conferences, which provided further supportive detail into pre-specified subgroup analyses and changes in kidney function.

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, information or public presentations with respect to: voclosporin being a potential treatment for LN; a PDUFA target action date of January 22, 2021; that we will continue to collaborate with the FDA during their review process and in parallel build our commercial readiness for a potential approval and commercial launch in the first quarter of 2021; voclosporin being potentially a best-in-class CNI; 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. 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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