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Aurinia Announces European Investigator-Initiated Trial to Evaluate Antiviral Activity of Voclosporin in Kidney Transplant Recipients with COVID-19

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 indications, today announced the funding and initiation of an open-label exploratory trial evaluating the antiviral effects of voclosporin in kidney transplant recipients (KTRs) with COVID-19 (SARS-CoV-2) – the VOCOVID study. The single-center, investigator-initiated trial (IIT) is being conducted by Drs. Aiko P.J. de Vries and Y.K. Onno Teng at the Leiden University Medical Center (LUMC) in the Netherlands and will compare voclosporin against tacrolimus.

"The COVID-19 pandemic has introduced new challenges for transplant recipients who require chronic immunosuppression to maintain their transplanted organ, which puts them at high risk for a more severe course after contracting COVID-19," said Aiko P.J. de Vries, M.D. Ph.D., Department of Nephrology at LUMC.

Onno Teng, MD, PhD, Department of Nephrology at the LUMC, commented, "we know from the previous PROMISE study that voclosporin can be dosed more predictably than legacy calcineurin inhibitors while maintaining the same degree of efficacy to prevent organ rejection. Preclinical data, which are being readied for peer-reviewed publication, from our institute in Leiden have demonstrated voclosporin's superior potency *in vitro* against SARS-CoV-2 compared to tacrolimus."

Organ transplant recipients who contract COVID-19 are at greater risk for complications due to the requirement of daily immunosuppressive medications to prevent organ rejection. Calcineurin inhibitors (CNIs), like voclosporin, have been shown in prior *in vitro* studies to inhibit viral replication. The team at the LUMC demonstrated that voclosporin inhibited viral replication of SARS-CoV-2 at an 8-fold lower concentration than tacrolimus *in vitro*, while maintaining cell viability of infected cells. In contrast to voclosporin, tacrolimus did not show antiviral activity against SARS-CoV-2 in vitro at clinically relevant concentrations. Therefore, given its potency and dosing advantages, voclosporin is a potentially attractive CNI for COVID-19 infected transplant patients who are already using legacy CNIs as part of their chronic immunosuppressive therapy.

"At Aurinia, we are dedicated to addressing the needs of people affected by serious diseases through scientifically rigorous and responsible drug development. Working with our long-time collaborators at LUMC, we established the preclinical antiviral activity of

voclosporin against the SARS-CoV-2 virus with results that further highlight voclosporin's differentiation from legacy CNIs," stated Robert Huizinga, Ph.D., R.N., CNeph(C), Executive Vice President, Research at Aurinia. "As we continue to prepare for potential FDA approval and commercial launch of voclosporin for the treatment of LN, we are pleased to test the potential of voclosporin to meet the urgent needs of this specific patient population driven by the COVID-19 pandemic."

About the VOCOVID Study

This 56-day open-label investigator initiated trial (IIT) is designed to evaluate the antiviral effects of voclosporin compared to tacrolimus in stable kidney transplant recipients (KTRs) who contracted SARS-CoV-2. At study entry, 20 KTRs testing positive for SARS-CoV-2 and currently on dual immunosuppressives of prednisone and tacrolimus will be randomized 1:1 to remain on tacrolimus or be switched to voclosporin. The primary endpoint is the reduction in SARS-CoV-2 viral load over 56 days, as measured by reverse transcription polymerase chain reaction (qRT-PCR). The study will also assess predefined endpoints as surrogate markers of improved viral clearance including time to 3-log reduction in viral load concentration, time to clinical recovery – defined as free of symptoms for five days or more, and safety and tolerability. Following the 56-day treatment period, there will be an extended safety follow-up of voclosporin treated patients for up to one year.

About Voclosporin

Voclosporin is a novel calcineurin inhibitor (CNI) developed to treat patients with lupus nephritis. By inhibiting calcineurin, voclosporin blocks IL-2 expression and reduces T-cell mediated immune responses while it synergistically stabilizes podocytes in the kidney. This novel CNI has a favorable metabolic profile and a consistent, predictable dose response potentially eliminating the need for therapeutic drug monitoring.

There are currently no therapies approved by the Food and Drug Administration (FDA) to treat lupus nephritis. Additionally, current SOC yields very low complete response rates. To help address the significant unmet medical need of lupus nephritis, the FDA designated voclosporin fast track status and priority review.

Voclosporin is currently not approved by the US FDA for any indication.

About Leiden University Medical Center

As a centre of medical innovation, Leiden University Medical Centre (LUMC) strives for a (inter)nationally recognised leading role in improving the quality of healthcare. The core tasks of the LUMC are research, education, patient care, training and continuing education. The LUMC is part of the Dutch Federation of University Medical Centres (NFU). The NFU is an alliance of the eight university medical centres (UMCs) in the Netherlands.

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 the investigational drug, voclosporin, for the potential treatment of lupus nephritis and evaluating voclosporin ophthalmic solution (VOS) in a Phase 2/3 study for the treatment of dry eye syndrome. The Company's head office is in Victoria, British Columbia and its U.S. commercial hub in Rockville, Maryland, 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: Aurinia's focus on advancing voclosporin in multiple indications; Aurinia's belief that voclosporin is a potentially attractive CNI and could have significant potential protective benefits for COVID-19 infected transplant patients who are already using legacy CNIs as part of their chronic immunosuppressive therapy; the potential results of the trial to evaluate antiviral activity of voclosporin in kidney transplant recipients with COVID-19; Aurinia's plans related to FDA regulatory approval and commercial launch for the use of voclosporin in LN; that voclosporin is a potentially best-in-class CNI; Aurinia's expectation 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; and that 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. 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; Aurinia may not be able to obtain sufficient supply to meet commercial demand for voclosporin in a timely fashion; unknown impact and difficulties imposed by the COVID-19 pandemic on our business operations including nonclinical, clinical, regulatory and commercial activities; and our assets or business activities may be subject to disputes that may result in litigation or other legal claims. 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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