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# **Aurinia Announces Collaboration and Licensing Agreement with Otsuka Pharmaceutical Co., Ltd. for the Development and Commercialization of Voclosporin in Europe and Japan**

*- Aurinia to receive \$50 million U.S. upfront payment in addition to up to \$50 million U.S. in regulatory and reimbursement milestone payments -*

*- Agreement includes royalties of up to 20 percent on net sales payable to Aurinia -*

VICTORIA, British Columbia & ROCKVILLE, Md.--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX:AUP) (“Aurinia” or the “Company”) today announced it has entered into a collaboration and license agreement with Otsuka Pharmaceutical Co., Ltd. for the development and commercialization of oral voclosporin for the treatment of Lupus Nephritis (LN) in the European Union (EU), Japan, as well as the United Kingdom, Russia, Switzerland, Norway, Belarus, Iceland, Liechtenstein and Ukraine.

As part of the agreement, Aurinia will receive an upfront cash payment of \$50 million U.S. and has the potential to receive up to \$50 million U.S. in regulatory and reimbursement milestone payments. Aurinia will receive tiered royalties ranging from 10 to 20 percent (dependent on achievement of sale milestones) on net sales upon commercialization, along with additional milestone payments based on the attainment of certain annual sales by Otsuka.

Voclosporin is a novel, investigational, orally administered treatment developed to treat patients with LN, a chronic, progressive inflammation of the kidneys that is one of the most serious complications of the autoimmune disease systemic lupus erythematosus (SLE).

The agreement leverages Otsuka’s well-recognized expertise in rare kidney diseases to underscore Aurinia’s commitment to expanding global access to voclosporin for the treatment of LN. Otsuka expects to file a marketing authorization application (MAA) with the European Medicines Agency (EMA) in Q2 2021 and will also manage the filing of voclosporin for LN with Pharmaceuticals Medical Devices Agency (PDMA) in Japan at a later date. Voclosporin is currently under review with the U.S. Food and Drug Administration (FDA) with an assigned Prescription Drug User Fee Act (PDUFA) target action date of January 22, 2021.

“Otsuka, with strong capabilities in nephrology and rare disease, is an ideal strategic partner to introduce voclosporin in Europe and Japan,” says Peter Greenleaf, President and Chief Executive Officer, Aurinia Pharmaceuticals. “This collaboration will provide Aurinia with

additional non-dilutive funds to focus on the successful U.S. launch of voclosporin and support plans to build our pipeline, while ensuring more lupus nephritis patients around the world can benefit from this potentially life-saving medication.”

Makoto Inoue, President and Representative Director of Otsuka Pharmaceutical Co., Ltd. commented, “Effective treatments for lupus nephritis are currently limited and a new treatment option such as voclosporin would be welcomed. We are pleased to enter the collaboration with Aurinia and look forward to delivering this drug to patients in Japan and Europe.”

## **About Lupus Nephritis**

LN is an inflammation of the kidney caused by 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 Voclosporin**

Voclosporin is a novel therapy in development for patients with LN, an inflammation of the kidney which is one of the most serious complications of the autoimmune disease SLE. If left untreated, LN can lead to irreversible kidney damage, kidney failure or even death. Through an extensive clinical program, voclosporin has demonstrated superiority to the standard-of-care for LN.

## **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 voclosporin for the potential treatment of LN. The Company's head office is in Victoria, British Columbia and its U.S. commercial hub is in Rockville, Maryland. The Company focuses its development efforts globally.

## **About Otsuka**

Otsuka Pharmaceutical is a global healthcare company with the corporate philosophy: "Otsuka-people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative products, with a focus on pharmaceutical products for the treatment of diseases and nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leader in the challenging area of mental health and has research programs on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate how Otsuka is a "big venture" company at heart, applying a youthful spirit of creativity in everything it does.

Otsuka Pharmaceutical is a subsidiary of Otsuka Holdings Co., Ltd., based in Japan. The Otsuka group of companies employed 47,000 people worldwide and had consolidated sales of approximately USD 13 billion in 2019.

All Otsuka stories start by taking the road less travelled. Learn more about Otsuka Pharmaceutical Company on its global website at <https://www.otsuka.co.jp/en>.

## **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 Company receiving up to \$50 million U.S. in regulatory and reimbursement milestone payments; the Company receiving tiered royalties ranging from 10 to 20 percent (dependent on achievement of sale milestones) and additional milestone payments based on annual sales by Otsuka; Otsuka filing an MAA with the EMA in Q2 2021; plans to build the Company's pipeline; the agreement with Otsuka ensuring more LN patients around the world benefit from voclosporin; and the Company's anticipated PDUFA date of January 22, 2021. 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 regulatory and reimbursement milestones will be achieved and the milestones payments made; and the FDA will not alter the PDUFA date; 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 including approval of marketing authorization applications and new drug approvals, as well as favourable product labeling; 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: Aurinia may not be able to obtain necessary regulatory approvals for commercialization of voclosporin in a timely fashion, or at all; the regulatory, reimbursement and sales milestones may not be achieved. 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](http://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](http://www.sec.gov/edgar).

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