

March 16, 2020



Aurinia Pharmaceuticals Initiates Rolling Submission of a New Drug Application to the U.S. Food and Drug Administration for Voclosporin in the Treatment of Lupus Nephritis

- Company remains on track to complete submission by the end of the second quarter 2020 -

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 in multiple indications, announced today that the Company has initiated a Rolling Submission of its New Drug Application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for voclosporin, a next-generation calcineurin inhibitor for the treatment of lupus nephritis (“LN”). The rolling NDA allows completed portions of an NDA to be submitted and reviewed by the Agency on an ongoing basis. Aurinia has submitted the Nonclinical Module and expects to complete the submission of all Modules by the end of the second quarter of 2020.

“Following a positive pre-NDA meeting with the FDA in February, we are pleased to initiate our rolling NDA submission to the Agency, a critical step toward making voclosporin available to patients as soon as possible. We look forward to working with the FDA throughout the process,” commented Larry Mandt, Senior Vice President, Quality and Regulatory Affairs at Aurinia.

Voclosporin was granted Fast Track designation by the FDA in 2016, with a Priority Review to be requested as part of the complete NDA submission anticipated by the end of Q2 2020.

About Aurinia

Aurinia Pharmaceuticals is a late clinical-stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are impacted by diseases with a high unmet medical need. The Company is currently developing an investigational drug for the treatment of LN, focal segmental glomerulosclerosis (“FSGS”) and dry eye syndrome (“DES”). The Company’s head office is in Victoria, British Columbia and focuses its development efforts globally. For further information, see our website at www.auriniapharma.com.

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: completing the submission of all modules to the FDA by the end of the second quarter of 2020; receiving a positive review of the NDA; and receiving approval during early 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: Aurinia being 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 global conditions may cause delays in regulation approvals, including those caused by or related to the novel coronavirus. 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 (including any delays caused or related to the novel coronavirus). 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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