

Aurinia Pharmaceuticals Announces Allowance of a New and Refined Method of Use Patent for LUPKYNIS® in the Treatment of Lupus Nephritis From the United States Patent and Trademark Office

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today announced that the United States Patent and Trademark Office (USPTO) has allowed a method of use patent application titled IMPROVED PROTOCOL FOR TREATMENT OF LUPUS NEPHRITIS. Aurinia's newly allowed U.S. Patent Application (No. 17/713,140) reflects the unique and proprietary dosing regimen of its currently marketed product, LUPKYNIS. Specifically, this patent further refines the method of using LUPKYNIS in combination with mycophenolate mofetil (MMF) and corticosteroids using eGFR as a method of pharmacodynamically dosing the product in patients with lupus nephritis. The newly allowed application provides patent coverage that supplements Aurinia's existing U.S. Patent No. 10,286,036, which is listed in the Orange Book and claims an FDA-approved method of using LUPKYNIS. The claims in this additional patent add further specificity on dosing consistent with the FDA approved product label. This patent has the potential to provide an additional layer of patent protection for LUPKYNIS up to 2037. The Company intends to list this newly allowed patent in the Orange Book once issued.

In addition, Aurinia is also announcing that it has recently received a Notice of Intention to Grant from the European Patent Office (EPO) for a patent application that has similar claims to Aurinia's existing method of use U.S. Patent No. 10,286,036. This European patent application was pursued through the Patent Cooperation Treaty (PCT) process. Once issued, this patent could provide protection up to 2037 across Europe.

"This allowance by the USPTO and the concomitant news from the European Patent Office further strengthens our Intellectual Property portfolio as it pertains to LUPKYNIS and its unique pharmacodynamic dosing protocol which is detailed in the FDA package insert. These new patents, once issued, will enhance the long-term potential of LUPKYNIS," said Peter Greenleaf, Chief Executive Officer of Aurinia.

About Lupus Nephritis

LN is a serious manifestation of SLE, a chronic and complex autoimmune disease. About 200,000-300,000 people live with SLE in the U.S. and about one-third of these people are diagnosed with lupus nephritis at the time of their SLE diagnosis. About 50 percent of all people with SLE may develop lupus nephritis. If poorly controlled, LN

can lead to permanent and irreversible tissue damage within the kidney. Black and Asian individuals with SLE are four times more likely to develop LN and individuals of Hispanic ancestry are approximately twice as likely to develop the disease when compared with Caucasian individuals. Black and Hispanic individuals with SLE also tend to develop LN earlier and have poorer outcomes when compared to Caucasian individuals.

About LUPKYNIS

LUPKYNIS® is the first U.S. FDA- and EC-approved oral medicine for the treatment of adult patients with active LN. LUPKYNIS is a novel, structurally modified calcineurin inhibitor (CNI) with a dual mechanism of action, acting as an immunosuppressant through inhibition of T-cell activation and cytokine production and promoting podocyte stability in the kidney. The recommended starting dose of LUPKYNIS is three capsules twice daily with no requirement for serum drug monitoring. Dose modifications can be made based on Aurinia's proprietary personalized eGFR-based dosing protocol. Boxed Warning, warnings, and precautions for LUPKYNIS are consistent with those of other CNI-immunosuppressive treatments.

About Aurinia

Aurinia Pharmaceuticals is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations that are impacted by serious diseases with a high unmet medical need. In January 2021, the Company introduced LUPKYNIS® (voclosporin), the first FDA-approved oral therapy for the treatment of adult patients with active lupus nephritis (LN). The Company's head office is in Victoria, British Columbia, its U.S. commercial hub is in Rockville, Maryland, and the Company 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 having patent protection to 2037; Aurinia's intention to list the newly allowed patent in the Orange Book once issued; and Aurinia's estimates as to the number of patients with SLE in the U.S. and the proportion of those persons who have developed LN at time of SLE diagnosis. It is possible that such results or conclusions may change. 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 accuracy of reported data from third party studies and reports; and that Aurinia's intellectual property rights are valid and do not infringe the intellectual property rights of third 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: the market for the LN business may not be as estimated; the results from Aurinia's clinical studies and from third party studies and reports may not be accurate; and Aurinia's assets or business activities may be subject to disputes that may result in litigation or other legal claims. Although Aurinia has 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 Aurinia's 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. 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 Report on Form 10-K and its other public available filings 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, and on Aurinia's website atwww.auriniapharma.com.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS

LUPKYNIS is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active LN. Limitations of Use: Safety and efficacy of LUPKYNIS have not been established in combination with cyclophosphamide. Use of LUPKYNIS is not recommended in this situation.

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS: MALIGNANCIES AND SERIOUS INFECTIONS

Increased risk for developing malignancies and serious infections with LUPKYNIS or other immunosuppressants that may lead to hospitalization or death.

CONTRAINDICATIONS

LUPKYNIS is contraindicated in patients taking strong CYP3A4 inhibitors because of the increased risk of acute and/or chronic nephrotoxicity, and in patients who have had a serious/severe hypersensitivity reaction to LUPKYNIS or its excipients.

WARNINGS AND PRECAUTIONS

Lymphoma and Other Malignancies: Immunosuppressants, including LUPKYNIS, increase the risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to increasing doses and duration of immunosuppression rather than to the use of any specific agent.

Serious Infections: Immunosuppressants, including LUPKYNIS, increase the risk of developing bacterial, viral, fungal, and protozoal infections (including opportunistic infections), which may lead to serious, including fatal, outcomes.

Nephrotoxicity: LUPKYNIS, like other CNIs, may cause acute and/or chronic nephrotoxicity. The risk is increased when CNIs are concomitantly administered with drugs associated with nephrotoxicity.

Hypertension: Hypertension is a common adverse reaction of LUPKYNIS therapy and may require antihypertensive therapy.

Neurotoxicity: LUPKYNIS, like other CNIs, may cause a spectrum of neurotoxicities: severe include posterior reversible encephalopathy syndrome (PRES), delirium, seizure, and coma; others include tremor, paresthesia, headache, and changes in mental status and/or motor and sensory functions.

Hyperkalemia: Hyperkalemia, which may be serious and require treatment, has been reported with CNIs, including LUPKYNIS. Concomitant use of agents associated with hyperkalemia may increase the risk for hyperkalemia.

QTc Prolongation: LUPKYNIS prolongs the QTc interval in a dose-dependent manner when dosed higher than the recommended lupus nephritis therapeutic dose. The use of LUPKYNIS in combination with other drugs that are known to prolong QTc may result in clinically significant QT prolongation.

Immunizations: Avoid the use of live attenuated vaccines during treatment with LUPKYNIS. Inactivated vaccines noted to be safe for administration may not be sufficiently immunogenic during treatment with LUPKYNIS.

Pure Red Cell Aplasia: Cases of pure red cell aplasia (PRCA) have been reported in patients treated with another CNI immunosuppressant. If PRCA is diagnosed, consider discontinuation of LUPKYNIS.

Drug-Drug Interactions: Avoid co-administration of LUPKYNIS and strong CYP3A4 inhibitors or with strong or moderate CYP3A4 inducers. Reduce LUPKYNIS dosage when co-administered with moderate CYP3A4 inhibitors. Reduce dosage of certain P-gp substrates with narrow therapeutic windows when co-administered.

ADVERSE REACTIONS

The most common adverse reactions (>3%) were glomerular filtration rate decreased, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.

SPECIFIC POPULATIONS

Pregnancy/Lactation: May cause fetal harm. Advise not to breastfeed.

Renal Impairment: Not recommended in patients with baseline eGFR ≤45 mL/min/1.73 m2 unless benefit exceeds risk. Severe renal impairment: Reduce LUPKYNIS dose.

Mild and Moderate Hepatic Impairment: Reduce LUPKYNIS dose. Severe hepatic impairment: Avoid LUPKYNIS use.

Please see Prescribing Information, including Boxed Warning, and Medication Guide for LUPKYNIS.

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