

December 15, 2020



# Aurinia and Lonza Announce Exclusive Agreement for Dedicated Voclosporin Manufacturing Capacity

***- State-of-the-Art Monoplant Will Provide Cost and Production Efficiency and Secure Active Pharmaceutical Ingredient (API) Supply for Future Commercial Demand -***

VICTORIA, British Columbia--(BUSINESS WIRE)-- **Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH / TSX: AUP) ("Aurinia")** and Lonza Ltd. (SIX: LONN) ("**Lonza**") today announced they have expanded their exclusive manufacturing relationship. The parties entered into a collaborative agreement to build a dedicated manufacturing capacity within Lonza's existing small molecule API facility in Visp, Switzerland. The dedicated facility (also referred to as "monoplant") will be equipped with state-of-the-art manufacturing equipment to provide cost and production efficiency for the manufacture of voclosporin, while expanding existing capacity and providing supply security to meet future commercial demand.

The new agreement builds on the parties' successful multi-year relationship. The agreement, which is conditional upon U.S. regulatory approval of voclosporin, does not impact the launch supply for voclosporin as this is secured by existing inventory. The monoplant is estimated to be operational in 2023.

"Lonza's world-class expertise and partnership have helped Aurinia to cost-effectively optimize the unique and complex manufacturing process required for the synthesis of voclosporin," said Peter Greenleaf, President and Chief Executive Officer of Aurinia Pharmaceuticals. "We are currently well-poised and ready with adequate product supply for launch and anticipated market demand. A dedicated production capability will help keep our manufacturing costs down and ensure long-term flexibility to meet future demand for years to come."

"This collaboration is a great example of how we can support both early and commercial-stage biopharmaceutical companies through innovation in manufacturing technology and flexible business models," said Gordon Bates, President Small Molecules Division, Lonza. "We are looking forward to further developing our relationship with Aurinia into a long and productive collaboration to supply this innovative medicine to patients across the globe."

Following U.S. regulatory approval of voclosporin, Aurinia will commence several capital expenditure payments. Upon completion of the monoplant, Aurinia will have the right to maintain unobstructed use of the monoplant by paying a quarterly fixed facility fee.

The U.S. Food and Drug Administration (FDA) accepted the filing of Aurinia's NDA for voclosporin in the treatment of lupus nephritis (LN), granted Priority Review, and assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 22, 2021.

### **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 systemic lupus erythematosus (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. Voclosporin is now under review by the FDA with Fast Track status and Priority Review as a potential therapy for LN in the United States.

### **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 Lonza**

At Lonza, we combine technological innovation with world class manufacturing and process excellence. Together, these enable our customers to deliver their discoveries in the healthcare, preservation, and protection sectors.

We are a preferred global partner to the pharmaceutical, biotech and specialty ingredients markets. We work to prevent illness and promote a healthier world by enabling our customers to deliver innovative medicines that help treat or even cure a wide range of diseases. We also offer a broad range of microbial control solutions, which help to create and maintain a healthy environment.

Founded in 1897 in the Swiss Alps, Lonza today operates in 120 sites and offices in more than 35 countries. With approximately 15,500 full-time employees, we are built from high-performing teams and of individual employees who make a meaningful difference to our own business, as well as the communities in which we operate. The company generated sales of CHF 5.9 billion in 2019 with a CORE EBITDA of CHF 1.6 billion. Find out more at [www.lonza.com](http://www.lonza.com) and follow us on Twitter @LonzaGroup or Facebook @LonzaGroupAG.

## **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: equipment at the monoplant facility being state-of-the-art; Aurinia expecting future commercial demand for voclosporin; the monoplant being operational by 2023; Aurinia being poised for increased adoption of and increased need for voclosporin; the PDUFA target action 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: monoplant buildout occurring on anticipated timelines; 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 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 we may experience in completing the development and commercialization of voclosporin; and the monoplant may have operational issues once underway that could result in production being limited or reduced from anticipated capacities; the monoplant could be subject to delays in construction, or construction may not be completed at all; the market for voclosporin for use in LN may not be as anticipated. 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).

**Additional Information and Disclaimer (Lonza)**

Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited ("SGX-ST"). Lonza Group Ltd is not subject to the SGX-ST's continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

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