

May 15, 2017



# **Aurinia Reports First Quarter 2017 Financial Results, Announces Initiation of Phase III Aurora Clinical Trial, and Provides Operational Highlights**

## **AURORA Phase III Trial with Voclosporin Has Been Initiated**

**Cash of \$202.1 million as of March 31, 2017, Providing Resources to Fund Company Through 2020**

## **AURA-LV Phase IIb Trial Met Key 48-Week Endpoints, Achieving Highest Complete Remission Rate of Any Global Lupus Nephritis Study**

**Cash of \$9.7 million used for operating activities in Q1 2017**

VICTORIA, British Columbia--(BUSINESS WIRE)-- Aurinia Pharmaceuticals Inc. (NASDAQ:AUPH) (TSX:AUP) ("Aurinia" or the "Company") has released its financial results for the first quarter ended March 31, 2017. Amounts, unless specified otherwise, are expressed in U.S. dollars.

"I am proud of the important clinical, regulatory and financial milestones our team has successfully achieved in our first quarter this year. We released positive 48-week results from our Phase IIb AURA-LV ("AURA") trial of voclosporin, which demonstrated significantly improved complete remission rates in patients suffering from lupus nephritis," said Richard Glickman, Aurinia's CEO and Chairman of the Board. "We also believe we have a clear path forward with regulators to develop voclosporin in major markets and have successfully funded the Company's initiated Phase III lupus nephritis clinical trial ("AURORA") and operations through 2020. Furthermore, based on the results of our AURA trial and regulatory feedback, we have moved diligently into our AURORA trial with several sites initiated and currently screening patients. Our clinical team is focused on continuing to initiate sites with an aggressive patient recruitment program. The AURORA trial design is consistent with that of the recently completed AURA clinical trial. We believe that the totality of data from both the AURORA and AURA trials will ultimately serve as the basis for a New Drug Application ("NDA") submission as well as regulatory submissions in other major global markets."

## **Recent operational highlights**

### **48-Week AURA-LV Data presented in Late Breaker Presentation at National Kidney Foundation 2017 Scientific Clinical Meeting**

On April 20, 2017 we announced additional 48-week results from the global AURA study in lupus nephritis ("LN") during the National Kidney Foundation 2017 Spring Clinical Meetings

in Orlando, FL. In addition to the trial meeting its complete and partial remission (“CR”/“PR”) endpoints at 48 weeks, all pre-specified secondary endpoints that have been analyzed to date were also met at 48 weeks. These pre-specified endpoints include: time to CR and PR (speed of remission); reduction in Systemic Lupus Erythematosus Disease Activity Index or SLEDAI score; and reduction in urine protein creatinine ratio (“UPCR”) over the 48-week treatment period. Notably, of the patients that achieved CR at 24 weeks, in the low-dose voclosporin group, 100% remained in CR at 48 weeks, which demonstrates durability of clinical response. Proteinuria levels and reduction in SLEDAI scores, which include non-renal measures of lupus activity, also continued to significantly separate over time versus the control group. Additional analyses are ongoing and will be presented at future medical and scientific meetings.

No unexpected safety signals were observed and voclosporin was generally well-tolerated, with the nature of adverse events consistent with what is expected of patients suffering from highly active LN while undergoing immunomodulation therapy. In the voclosporin arms, the renal function as measured by eGFR was stable and not significantly different from the control arm during the 48-week treatment period. Mean blood pressure was also similar between all treatment groups.

The 24 and 48-week efficacy results are summarized below:

Endpoint	Treatment	24 weeks	P-value*	48 weeks	P-value*
Complete Remission (CR)	<b>23.7mg VCS BID</b>	<b>33%</b>	<b><i>p</i>=.045</b>	<b>49%</b>	<b><i>p</i>&lt;.001</b>
	39.5mg VCS BID	27%	<i>p</i> =.204	40%	<i>p</i> =.026
	Control Arm	19%	NA	24%	NA
Partial Remission (PR)	<b>23.7mg VCS BID</b>	<b>70%</b>	<b><i>p</i>=.007</b>	<b>68%</b>	<b><i>p</i>=.007</b>
	39.5mg VCS BID	66%	<i>p</i> =.024	72%	<i>p</i> =.002
	Control Arm	49%	NA	48%	NA
Time to CR (TTCR) [median]	<b>23.7mg VCS BID</b>	<b>19.7 weeks</b>	<b><i>p</i>&lt;.001</b>	<b>19.7 weeks</b>	<b><i>p</i>&lt;.001</b>
	39.5mg VCS BID	23.4 weeks	<i>p</i> =.001	23.4 weeks	<i>p</i> <.001
	Control Arm	NA	NA	NA	NA
Time to PR (TTPR) [median]	<b>23.7mg VCS BID</b>	<b>4.1 weeks</b>	<b><i>p</i>=.002</b>	<b>4.3 weeks</b>	<b><i>p</i>=.005</b>
	39.5mg VCS BID	4.4 weeks	<i>P</i> =.003	4.4 weeks	<i>p</i> =.002
	Control Arm	6.6 weeks	NA	6.6 weeks	NA
SLEDAI Reduction (non-	23.7mg VCS BID	-6.3	<b><i>p</i>=.003</b>	-7.9	<b><i>p</i>&lt;.001</b>

<b>renal lupus)</b>	39.5mg VCS BID	-7.1	<i>p</i> =.003	-8.3	<i>p</i> <.001
	Control Arm	-4.5	NA	-5.3	NA
<b>Reduction in UPCR</b>	<b>23.7mg VCS BID</b>	<b>-3.769 mg/mg</b>	<b><i>p</i>&lt;.001</b>	<b>-3.998 mg/mg</b>	<b><i>p</i>&lt;.001</b>
	39.5mg VCS BID	-2.792 mg/mg	<i>p</i> =.006	-2.993 mg/mg	<i>p</i> =.008
	Control Arm	-2.216 mg/mg	NA	-2.384 mg/mg	NA

Note: "VCS" means voclosporin

\*All *p*-values are vs control

## Regulatory pathway forward

On April 7, 2017 we announced the outcome of discussions with both the European Medicines Agency (EMA) and the Pharmaceutical and Medical Devices Agency (PMDA) in Japan regarding the development of voclosporin for the treatment of active LN. Pursuant to these discussions, we believe that the confirmatory data that can be generated from the AURORA trial and the recently completed AURA trial should support regulatory submissions in the US, Europe and Japan.

The AURORA trial will be a global 52-week double-blind, placebo controlled study of approximately 320 patients. Patients will be randomized 1:1: to either of 23.7mg voclosporin BID and mycophenolate mofetil (MMF) or MMF and placebo, with both arms receiving a stringent oral corticosteroid taper. As in AURA, the study population will be comprised of patients with biopsy-proven active LN who will be evaluated on the primary efficacy endpoint of complete remission, or renal response, at 52 weeks, a composite which includes:

- UPCR of  $\leq 0.5$ mg/mg
- Normal, stable renal function ( $\geq 60$  mL/min/1.73m<sup>2</sup> or no confirmed decrease from baseline in eGFR of  $>20\%$ )
- Presence of sustained, low dose steroids ( $\leq 10$ mg prednisone from week 16-24)
- No administration of rescue medications throughout the treatment period

## Key Developments in First Quarter, 2017

### Completion of Public Offering

On March 20, 2017 we announced the closing of an underwritten public offering of 25.64 million common shares. The shares were sold at a public offering price of \$6.75 per share. The gross offering proceeds to the Company from this Offering were US\$173.1 million. Expenses of the offering including underwriting commissions and other offering expenses were \$10.8 million.

### AURA 48-Week Results

On March 1, 2017, we announced top-line results from the AURA trial. At 48 weeks, the trial

met the CR/PR endpoints, demonstrating statistically significant greater CR and PR in patients in both low dose (23.7mg of voclosporin twice daily ( $p < .001$ )) and high dose (39.5mg twice daily ( $p = .026$ )) cohorts versus the control group. No unexpected safety signals were observed and there were no additional deaths in the voclosporin treated patients; however, there were three deaths and one malignancy reported in the control arm after completion of the study treatment period.

### **Japanese Phase I Ethnic Bridging Study for Voclosporin**

On February 14, 2017, we announced results of a supportive Phase I safety, pharmacokinetic (“PK”) and pharmacodynamics (“PD”) study in healthy Japanese patients, which supports further development of voclosporin in this patient population. Based on evaluations comparing the Japanese ethno-bridging data vs. previous PK and PD studies in non-Japanese patients, voclosporin demonstrated no statistically significant differences in exposure with respect to Area Under the Curve measurements. Furthermore, the PK parameters in Japanese patients were generally consistent with previously evaluated PK parameters in non-Japanese volunteers. There were no unusual or unexpected safety signals in the study.

### **Financial Results for the First Quarter Ended March 31, 2017**

As a result of completing the public offering on March 20, 2017, Aurinia had cash, cash equivalents and short term investments of \$202.1 million as at March 31, 2017 compared to \$39.6 million as at December 31, 2016. We believe, based on our current plans, that we have the financial resources to complete the AURORA trial and fund operations through 2020.

Cash used in operating activities for the three months ended March 31, 2017 was \$9.7 million. Cash provided by financing activities was \$172.2 million comprised of net proceeds of \$162.3 million from the public offering and \$9.9 million from the exercise of warrants and stock options during the three month period ended March 31, 2017.

For the first quarter ended March 31, 2017, we reported a consolidated net loss of \$51.9 million or \$0.92 per common share. This loss included a non-cash increase of \$40.8 million related to the estimated fair value quarterly adjustment of derivative warrant liabilities at March 31, 2017. After adjusting for this non-cash impact, the net loss from operations was \$11.2 million or \$0.20 per common share.

This compared to a consolidated net loss of \$4.3 million or \$0.13 per common share, which included a non-cash decrease on revaluation of derivative warrant liability of \$664,000 at March 31, 2016. After adjustment for the non-cash impact of the revaluation, the net loss from operations for the three months ended March 31, 2016 was \$4.9 million or \$0.15 per common share.

The change in the revaluation of the derivative warrant liabilities is primarily driven by the change in our share price. Our share price was significantly higher at March 31, 2017 compared to December 31, 2016 which resulted in a large fair value adjustment. These derivative warrant liabilities will ultimately be transferred to equity upon the exercise or expiry of these warrants and therefore are non-cash adjustments.

We incurred net research and development expenditures of \$7.3 million for the first quarter ended March 31, 2017, as compared to \$3.3 million for the same period in 2016. The increase in research and development expenditures in 2017 reflected initiation costs, including activities such as clinical site selections and regulatory submissions and drug manufacturing costs related to the AURORA trial and completion costs associated with the AURA trial.

We incurred corporate, administration and business development costs of \$3.4 million for the first quarter ended March 31, 2017, as compared with \$1.2 million for the same period in 2016. These costs included a non-cash stock compensation expense of \$1.1 million in 2017 compared to \$261,000 in 2016 primarily due to an increase in the number of options granted in 2017 compared to the same period in 2016.

This press release should be read in conjunction with the our unaudited interim condensed consolidated financial statements and the MD&A for the first quarter ended March 31, 2017 which are accessible on Aurinia's website at [www.auriniapharma.com](http://www.auriniapharma.com), on SEDAR at [www.sedar.com](http://www.sedar.com) or on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).

### ***About AURORA***

The AURORA trial is a 52-week global double-blind placebo controlled phase III trial that will compare the efficacy of one dose of voclosporin (23.7mg BID) or placebo added to current standard of care of mycophenolate mofetil (MMF, also known as CellCept®) in achieving renal response (formerly referred to as complete remission) in patients with active LN. Both arms will also receive corticosteroids as part of background therapy. These corticosteroids will be stringently and aggressively tapered over the course of the trial.

### ***About AURA-LV***

The AURA–LV trial (Aurinia Urinary Protein Reduction in Active Lupus with Voclosporin) was a 48-week trial comparing the efficacy of two doses of voclosporin added to current standard of care of MMF against standard of care with placebo in achieving CR in patients with active LN. All arms also received low doses of corticosteroids as background therapy. 265 patients were enrolled at centers in 20 countries worldwide. On entry to the study, patients were required to have a diagnosis of LN according to established diagnostic criteria (American College of Rheumatology) and clinical and biopsy features indicative of highly active nephritis. The 24-week primary and secondary endpoints were released in Q3 2016 with top-line 48-week results announced in Q1 2017. The 48-week data was presented at a late-breaking presentation at National Kidney Foundation (NKF) Spring Clinical Meeting which took place April 18-22 in Orlando, FL.

### ***About Voclosporin***

Voclosporin, an investigational drug, is a novel and potentially best-in-class calcineurin inhibitor (“CNI”) with clinical data in over 2,200 patients across indications. Voclosporin is an immunosuppressant, with a synergistic and dual mechanism of action that has the potential to improve near- and long-term outcomes in LN when added to standard of care (MMF). By inhibiting calcineurin, voclosporin blocks IL-2 expression and T-cell mediated immune responses. It is made by a modification of a single amino acid of the cyclosporine molecule which has shown a more predictable pharmacokinetic and pharmacodynamic relationship,

an increase in potency, an altered metabolic profile, and potential for flat dosing. The Company anticipates 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.

### ***About Lupus Nephritis (LN)***

LN is an inflammation of the kidney caused by Systemic Lupus Erythematosus (“SLE”) and represents a serious progression of SLE. SLE is a chronic, complex and often disabling disorder and affects more than 500,000 people in the United States (mostly women). The disease is highly heterogeneous, affecting a wide range of organs & tissue systems. It is estimated that as many as 60% of all SLE patients have clinical LN requiring treatment. Unlike SLE, LN has straightforward disease outcomes where an early response correlates with long-term outcomes, measured by proteinuria. In patients with LN, renal damage results in proteinuria and/or hematuria and a decrease in renal function as evidenced by reduced estimated glomerular filtration rate (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 Aurinia***

Aurinia is a clinical stage biopharmaceutical company focused on developing and commercializing therapies to treat targeted patient populations that are suffering from serious diseases with a high unmet medical need. The Company is currently developing voclosporin, an investigational drug, for the treatment of LN. The Company is headquartered in Victoria, BC and focuses its development efforts globally.

### ***Forward-Looking Statements***

This press release contains forward-looking statements, including statements around our analysis, assessment and conclusions around the future development and commercial potential of voclosporin; our belief that we have a clear path forward with regulators to develop voclosporin in major markets; our belief that we have fully funded our AURORA Phase III clinical trial and operations through 2020; our belief that our prior clinical trial results will serve as the basis for a NDA submission and regulatory submissions in major global markets; and our expectation that 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; and the timing of future clinical trials; summary statements relating to results of the past voclosporin trials; the timing of commencement and completion of clinical trials; and plans and objectives of management.

It is possible that such results or conclusions may change based on further analyses of these data. Words such as "plans," "intends," "may," "will," "believe," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Aurinia's current expectations. Forward-looking statements involve risks and uncertainties. Aurinia's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risk that Aurinia's analyses, assessment

and conclusions of the results of the future development and commercial potential of voclosporin set forth in this release may change based on further analyses of such data, and the risk that Aurinia's clinical studies for voclosporin may not lead to regulatory approval. These and other risk factors are discussed under "Risk Factors" and elsewhere in Aurinia's Annual Information Form for the year ended December 31, 2016 filed with Canadian securities authorities and available at [www.sedar.com](http://www.sedar.com) and on Form 40-F with the U.S. Securities Exchange Commission and available at [www.sec.gov](http://www.sec.gov), each as updated by subsequent filings, including filings on Form 6-K. Aurinia expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Aurinia's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to differ materially from any further results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause such differences include, among other things, the following:

- difficulties, delays, or failures we may experience in the conduct of its planned AURORA clinical trial;
- difficulties we may experience in completing the development and commercialization of voclosporin;

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These forward-looking statements are made as of the date hereof and will only be updated in accordance with applicable law.

*We seek Safe Harbor.*

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