



# Changing the course of autoimmune disease

39<sup>th</sup> Annual J.P. Morgan Healthcare Conference  
January 14, 2021



# Forward Looking Statements

Certain statements made in this slide presentation 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 NDA priority review submissions in a successful and timely manner including the anticipated PDUFA action date of January 22, 2021; the potential for commercial launch of voclosporin for use in LN in 2021; voclosporin being potentially a best-in-class CNI with robust intellectual property exclusivity and protection; Aurinia's anticipation that upon regulatory approval, patent protection for voclosporin composition of matter 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 and until April 2028 with anticipated pediatric extension; a U.S. patent has also been issued covering the voclosporin dosing protocol with a term extending to December 2037, if the FDA adequately incorporates the dosing protocol used in both the AURA and the AURORA studies into the product label; that the results of the AURORA clinical study are pivotal; that voclosporin may be positioned to become the standard of care for people living with LN; that Aurinia will present AURORA study results at a future scientific conference during 2020. 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 market value for the LN program; that another company will not create a substantial competitive product for Aurinia's LN business without violating Aurinia's intellectual property rights; the burn rate of Aurinia's cash for operations; the costs and expenses associated with Aurinia's clinical trials; the planned studies achieving positive results; Aurinia being able to extend and protect its patents for LN on terms acceptable to Aurinia; and the size of the LN market; 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 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: difficulties, delays, or failures we may experience in the conduct of our clinical trial; difficulties we may experience in completing the development and commercialization of voclosporin; the market for the LN business may not be as estimated; Aurinia may have to pay unanticipated expenses; estimated costs for clinical trials may be underestimated, resulting in Aurinia having to make additional expenditures to achieve its current goals; Aurinia not being able to extend or fully protect its patent portfolio for voclosporin; competitors may arise with similar products; Aurinia may not be able to obtain necessary regulatory approvals for commercialization of voclosporin in a timely fashion, or at all; and Aurinia may not be able to obtain sufficient supply to meet commercial demand for voclosporin in a timely fashion. 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).

# Leadership Built on a Legacy of Innovation

Aurinia's mission is to transform people's lives by delivering therapeutics that change the course of autoimmune disease

- We are translating decades of voclosporin research into a potentially groundbreaking therapeutic for lupus nephritis – NDA currently under FDA review
- We are building our global leadership in biopharma for patients with autoimmune diseases. Our strategy combines medical innovation with deep patient community engagement and commercial expertise to deliver long-term value to patients and the healthcare system.
- Well capitalized to launch voclosporin and achieve our business imperatives



# An Emerging Therapeutic Leader In Lupus Nephritis (LN)



LN is a progressive, potentially life-threatening inflammation of the kidneys that creates significant burden on patients and the healthcare system



Voclosporin in development as a potential first oral approved treatment for LN in the U.S. supported by comprehensive clinical data



Aurinia is deeply engaged with the lupus nephritis community who have been historically underserved without approved treatments for LN



Aurinia is launch ready ahead of January 22, 2021 PDUFA action date

# A Strong Foundation For Success



## **Potential groundbreaking FDA approval for voclosporin**

- Granted FDA Priority Review with a PDUFA date in January 2021
- Potential first FDA approval for oral lupus nephritis drug
- Extensive launch preparations and pioneering engagement with the LN community underway



## **Established foundation for long-term growth**

- Leadership with extensive experience in commercial launches and renal therapeutics
- Established ex-U.S. partnership with Otsuka
- Robust IP with potential for protection through 2037
- Pursuing new voclosporin indications and broader pipeline growth strategy
- Cash and equivalents of \$421M at 9/30/20: Projected to fund operations through 2022

# Voclosporin: Pioneering potential in lupus nephritis

- Differentiated clinical profile on multiple parameters
- Major need in community with unaddressed disease burden

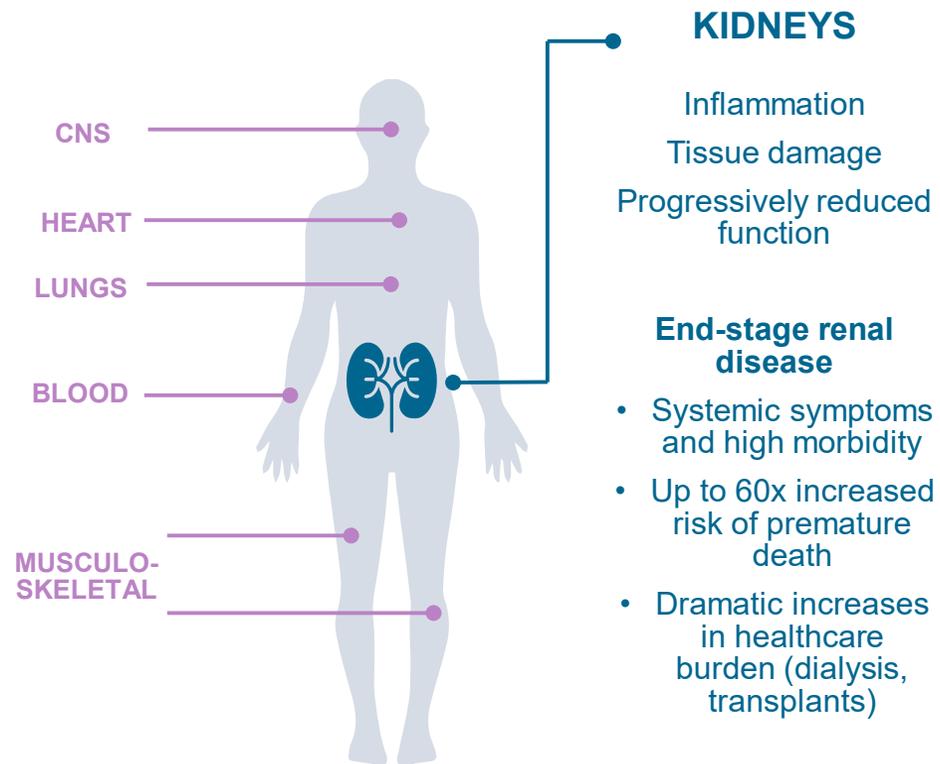


# Lupus Nephritis: Underserved Condition with Urgent Unmet Need

A serious, progressive inflammation of the kidneys in people with SLE

Systemic lupus erythematosus (SLE)

Lupus nephritis (LN)



Major opportunity for a novel therapeutic

- No FDA or EMA-approved oral therapies
- Up to 40% of SLE patients develop LN
- Fast, early and effective intervention can change the course of disease and prevent end-stage disease
  - Voclosporin clinical data supports ability to deliver on all parameters

# Voclosporin: Next-Generation Clinical Profile for LN and Beyond

*Over LN standard-of-care (unapproved medications)*



**Stronger clinical response profile**



**Faster clinical response**



**All oral dosing**

*Over first-generation calcineurin inhibitors (CNIs)*



**More predictable metabolism - no therapeutic drug monitoring required**



**Better glucose profile – reduced risk of diabetes<sup>1</sup>**



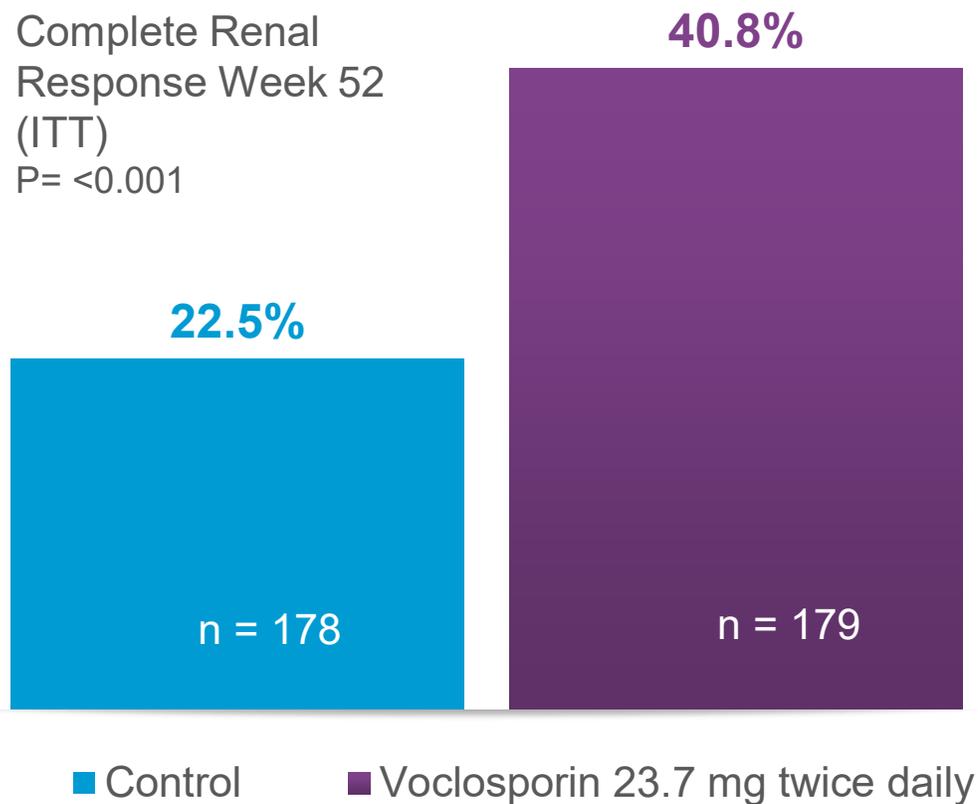
**Increased potency and improved lipid profile<sup>2</sup>**

- Voclosporin retains the uniquely effective mechanism of CNIs that provides optionality in a range of autoimmune conditions, but has a substantially improved clinical profile
- A comprehensive clinical program supports superiority over LN standard-of-care, including higher rates of partial and complete responses and a doubled speed of proteinuria reduction

1. Versus tacrolimus  
2. Versus cyclosporine A

# AURORA Phase 3 Pivotal Study: Superiority Across Endpoints

## ✓ Primary Endpoint



## ✓ Secondary Endpoints

Measure	Result	p-value
Complete Renal Response at Week 24	Voclosporin 32.4% Control 19.7%	0.002
Partial Renal Response at Week 24	Voclosporin 70.4% Control 50.0%	< 0.001
Partial Renal Response at Week 52	Voclosporin 69.8% Control 51.7%	< 0.001
Time to UPCR ≤ 0.5 mg/mg	Voclosporin faster than Control	< 0.001
Time to 50% reduction in UPCR	Voclosporin faster than Control	< 0.001

**Safety equivalent to standard-of-care**  
**Three-year data from AURORA 2 extension study expected 4Q21**

Abbreviations: ITT = intent to treat; UPCR = urinary protein to creatinine ratio

# Voclosporin: Robust Intellectual Property

- Composition of Matter protection for voclosporin in the U.S. is anticipated until at least
- October 2027 under the Hatch-Waxman Act and comparable laws in other countries



- United States Patent and Trademark Office (“USPTO”) granted in May 2019 for the novel voclosporin dosing protocol based on patient specific pharmacodynamic parameters (#10,286,036)
- Patent provides protection up to **December 2037** contingent upon product approval and corresponding label

\*Similar coverage periods are assumed for the CoM patents in Europe & Japan, the Methods patents have been filed under PCT and will be examined in due course

# Voclosporin Positioned as a Fast, Effective and Safe Therapy for LN

## Unmet Medical Need

## Voclosporin

Based on AURORA Phase 3 Study Results

Control of Active Disease



Rapid Disease Control



Reduced Steroid Burden



Convenient Treatment Regimen



# Voclosporin launch strategy

- World-class commercial team in place with high-touch model
- Deep community and HCP engagement program underway



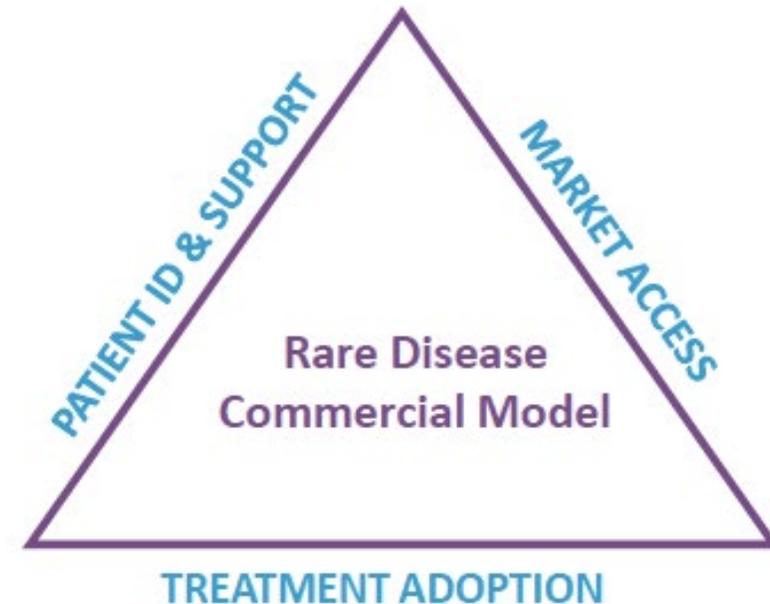
# Our Vision: Voclosporin as a Potential First Oral Therapy for Lupus Nephritis

## We are committed to delivering:

- A therapeutic option that will help bring lupus nephritis out of the shadows and inspire a new level of consideration for kidney health in SLE
- A new standard of care for new and uncontrolled or unresponsive lupus nephritis patients based on a comprehensive and strongly supportive clinical program
- The resources, education and advocacy to elevate importance of early diagnosis, referral and continuous management to inspire earlier and more sustained remissions so patients can live better and longer

# Full U.S. Launch Preparations Underway With High Touch Model

- Exemplary commercial team with significant launch experience
- High-touch rare disease commercial model
  - Emphasis on patient identification and support, market access and treatment adoption
  - Expert field team with particular experience in rare and renal disease engagement
  - Specialized resources at each step of patient journey



## In place:



**Experienced leadership**



**KOL liaisons**



**Account directors**



**Medical science liaisons**

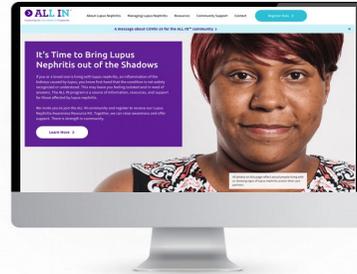


**Sales force**



**Patient care managers**

# Pioneering Engagement with the Lupus Nephritis Community



- ALL IN is the first and only company-sponsored disease education and advocacy platform for the lupus nephritis community
- Digital and physical assets to elevate the patient voice, educate and advocate for the LN community
- Shines a light on patient experience of diagnosis, treatment, symptoms, economic and quality-of-life burden



- Deep relationships with leading lupus and kidney patient advocacy and research groups
- Ongoing engagement and company-wide participation in disease awareness events



- TimelsNephrons is the first-ever LN disease-state awareness initiative for HCPs
- Initiative aims to highlight the important of active screening for early diagnosis to improve long-term health outcomes

# Established Partnerships for Global Access and Future Demand

- Collaboration and licensing agreement for the development and commercialization of LUPKYNIS in the EU and Japan (+ additional ex-US markets)
- Leverages Otsuka's well-recognized expertise in rare kidney disease
- \$50 million U.S. upfront cash payment; Potential for up to \$50 million U.S. in regulatory and reimbursement milestone payments
- Tiered royalties ranging from 10 to 20% on net sales
- Product purchased at cost of goods plus



- Established initial relationship in 2016
  - Lonza's world-class expertise has helped Aurinia optimize the unique and complex LUPKYNIS manufacturing process
- Exclusive agreement with Lonza to build dedicated, state-of-the-art "monoplant" to ensure cost and production efficiency and secure LUPKYNIS API supply for future demand
- Upon completion, Aurinia will have the right to maintain unobstructed use by paying a quarterly fixed facility fee

**Lonza**

# Summary



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