# Quality of life in CRS patients treated with long-acting implantable corticosteroid matrices

## Anders Cervin, MD, PhD, FRACS

Professor of Otolaryngology

University of Queensland Centre for Clinical Research

Royal Brisbane & Women's Hospital

Herston, Queensland, Australia

ARS at COSM 2022: Dallas, Texas, April 28-29, 2022

## DISCLOSURES

• Anders Cervin was a clinical investigator in the LANTERN Phase 2 randomized controlled study

# CHRONIC RHINOSINUSITIS (CRS)

- CRS is highly prevalent and negatively impacts patients' quality of life (QOL)
- CRS patients exhibit persistent sinonasal symptoms, often accompanied by fatigue, sleep disruption, and/or depression that affects their overall well-being and productivity
- No FDA-approved therapies for CRS without nasal polyps
- Long-acting effective treatments for chronic rhinosinusitis are needed that deliver a therapeutic daily dose of anti-inflammatory medication directly to the sinonasal mucosa and improve the QOL of patients

## LYR-210 FOR CRS

### LYR-210 is designed for CRS patients who failed previous medical management

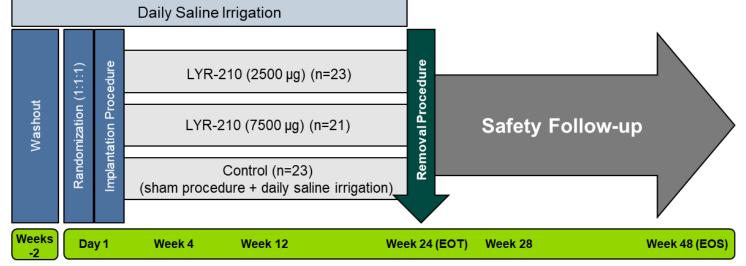
- Continuously delivers a therapeutic dose of mometasone furoate deep in the sinonasal passages
- Provides up to 24-weeks of benefit from a single administration
- Self-expanding properties allowing it to dynamically conform to the middle meatus
- Straightforward office-based placement and removal
- Improves patient compliance





# LANTERN PHASE 2 STUDY DESIGN





Study enrollment was curtailed to 67 total subjects due to the COVID-19 global pandemic

Study Population: Adults with CRS who failed previous medical management and have not undergone FESS

Approximately half had nasal polyps

Primary Endpoint: Composite of CRS cardinal symptoms\*

### Secondary Endpoints:

- SNOT-22
- Individual Cardinal Symptoms
- Ethmoid Opacification (MRI)
- Time to first rescue treatment
- Adverse events

\*CRS cardinal symptoms are nasal blockage, facial pain/pressure, nasal discharge, and olfactory loss

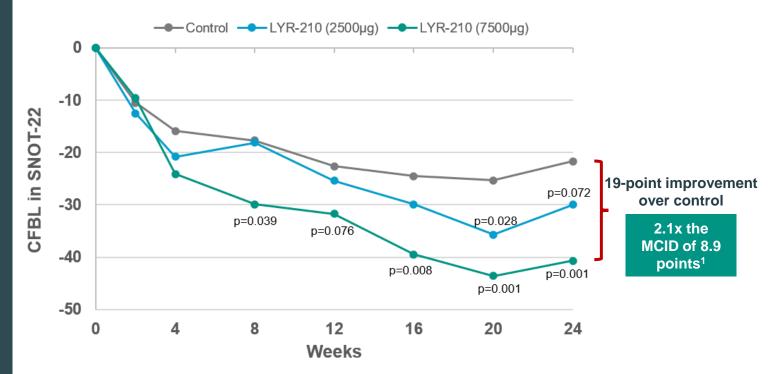
EOT = End of Treatment; EOS = End of Study

## LANTERN STUDY

LYR-210 (7500µg) demonstrated safety and statistically significant and clinically meaningful benefit in:

- Cardinal symptom composite scores
- Reduced need for rescue treatment
- Ethmoid opacification (MRI)

# LYR-210 achieved rapid, durable, and dose-dependent global CRS improvement over 24 weeks in SNOT-22



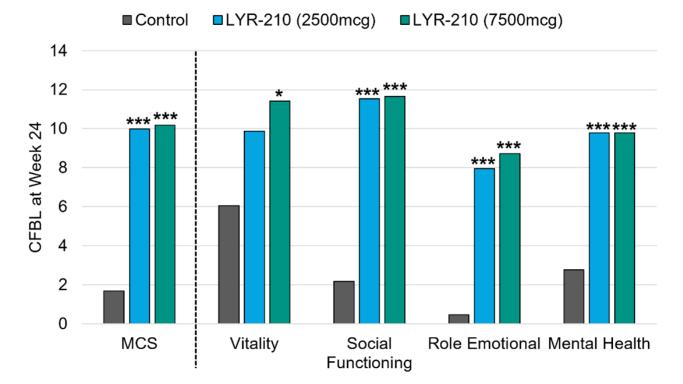
All patients administered LYR-210 (7500µg) achieved MCID of 8.9 points by week 24

## SF-36V2: GENERIC QUALITY OF LIFE ASSESSMENT

- SF-36v2 = 36-item short form health survey, version 2
- Validated and frequently used patient-reported outcome instrument to measure physical and mental health in clinical trials across multiple diseases
- Comprised of 8 health domain scales and psychometrically based physical component summary (PCS) and mental component summary (MCS) scores
  - <u>Mental Component Domains</u>: vitality, social functioning, role-emotional, mental health
  - <u>Physical Component Domains</u>: physical functioning, role-physical, bodily pain, general health
- Higher SF-36v2 scores represent a better health-related quality of life
- LANTERN study subjects completed the SF-36v2 at baseline (before placement procedure) and week 24

## SF-36V2 MENTAL COMPONENT SCORES AT WEEK 24

LYR-210 (7500µg) demonstrated statistically significant improvement in the mental component summary (MCS) score and all four domain scales compared to control

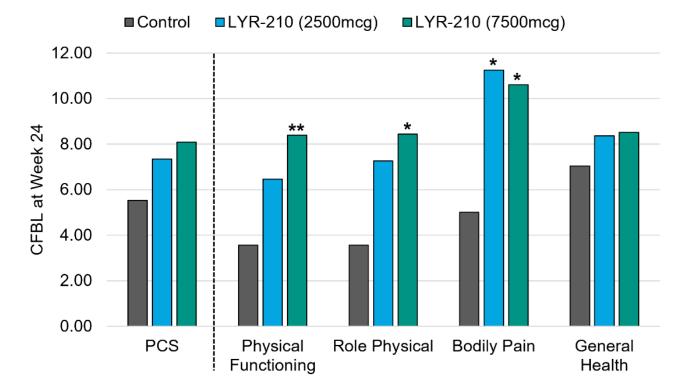


#### Mental Component Scores

Data represents LS means. CFBL=change from baseline; MCS=mental component summary. *P*-values are 1-sided vs. Control \* *p*<0.05; \*\* *p*<0.025; \*\*\* *p*<0.01.

## SF-36V2 PHYSICAL COMPONENT SCORES AT WEEK 24

LYR-210 (7500µg) demonstrated statistically significant improvement vs. control in the mean CFBL in physical functioning, role physical, and bodily pain

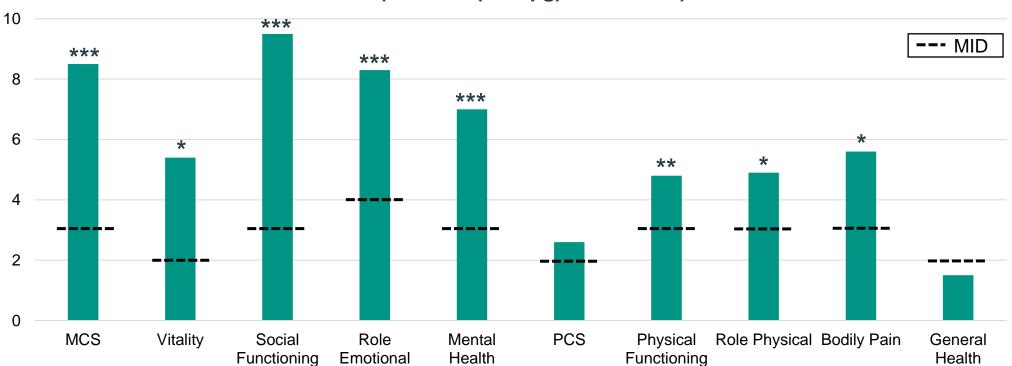


#### **Physical Component Scores**

Data represents LS means. CFBL=change from baseline; PCS=physical component summary. *P*-values are 1-sided vs. Control \* *p*<0.05; \*\* *p*<0.025; \*\*\* *p*<0.01.

## **RESPONDER ANALYSIS OF SF-36V2 SCORES AT WEEK 24**

LYR-210 (7500µg) demonstrated statistically significant and clinically important improvement vs. control in the mean CFBL in MCS and all individual scales except general health



LS Mean Difference (LYR-210 (7500µg) vs. Control) in CFBL at Week 24

CFBL=change from baseline; MCS=mental component summary; PCS=physical component summary; MID=minimally important difference . *P*-values are 1-sided. \* *p*<0.05; \*\* *p*<0.025; \*\*\* *p*<0.01. Maruish ME (Ed.). User's manual for the SF-36v2 Health Survey (3rd ed.). Lincoln, RI: QualityMetric Incorporated. 2011.

## CONCLUSIONS

## LYR-210 (7500µg) may improve the mental and physical health and QOL of CRS patients

- LYR-210 reported higher scores than control in all SF-36v2 domains
- LYR-210 (7500µg) significantly improved the MCS and the 4 mental component domain scores, as well as physical functioning, role-physical, and bodily pain at week 24
- SF-36v2 results are consistent with the effect of LYR-210 (7500µg) on SNOT-22, a CRS-specific assessment of disease burden and QOL, which achieved a significant 40-point reduction from baseline at week 24
- Study limitation includes smaller numbers of enrolled subjects than planned due to COVID-19 pandemic
- LYR-210 (7500µg) is being evaluated in a 2 parallel multicenter, blinded, randomized, controlled Phase 3 trials