



Lyra Therapeutics Presents Positive Data from LANTERN Phase 2 Study of LYR-210 for Treatment of Chronic Rhinosinusitis at COSM 2022

April 29, 2022

LYR-210 provided up to 24 weeks of clinically meaningful global symptom improvement in CRS patients

LYR-210 achieved significant improvement in each CRS symptom subdomain of the SNOT-22 compared to control

LYR-210 may improve mental and physical health and quality of life of CRS patients

WATERTOWN, Mass., April 29, 2022 /PRNewswire/ -- Lyra Therapeutics, Inc. (Nasdaq: LYRA), a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, and local delivery of medications to the ear, nose and throat (ENT) passages and other diseased tissues, today is presenting additional, new data from its LANTERN Phase 2 study of LYR-210 in adult patients with chronic rhinosinusitis (CRS) at the 2022 Combined Otolaryngology Spring Meetings (COSM) being held April 27 – May 1, 2022 in Dallas, Texas. LYR-210 is designed as an alternative to sinus surgery for the millions of CRS patients that remain symptomatic despite treatment.

Anders Cervin, MD, PhD, Professor Chair in Otolaryngology at the Centre for Clinical Research, Royal Brisbane & Women's Hospital Campus, Herston, in Queensland Australia, and an investigator in the LANTERN study, is presenting the data.

"These positive data build on the LANTERN Phase 2 results supporting our belief in LYR-210's meaningful improvement of patients' CRS symptoms and quality of life," said Dr. Cervin. "Using the SNOT-22 score, a validated tool for assessing patients' symptoms and guiding their treatment, we were pleased to see that LYR-210 drove improvements in all five SNOT-22 sub-domains as well as the SF-36, a widely used clinical measure of quality of life."

"These encouraging LANTERN data demonstrate the potential of LYR-210 to transform the treatment paradigm for CRS patients who still experience debilitating symptoms with current treatment approaches," said Robert Kern, MD, Chief Medical Officer of Lyra Therapeutics. "We look forward to further advancing LYR-210 through the clinic in the ENLIGHTEN Phase 3 program, which was initiated earlier this year."

Summary of Data Presented

Impact of long-acting implantable corticosteroid matrices on SNOT-22 subdomains in CRS patients: selected as COSM 2022 top-rated clinical abstract by the American Rhinologic Society

The 22-item sino-nasal outcome test (SNOT-22) is a validated and routinely used CRS-specific quality of life questionnaire consisting of five subdomains: rhinologic, extra-nasal rhinologic, ear/facial, psychological dysfunction, and sleep dysfunction. Higher scores indicate higher severity of symptoms and/or social and emotional consequences.

Key results include:

- LYR-210 (7500µg)-treated subjects reported dose-dependent global symptom improvement, achieving statistical significance ($p < 0.05$) in each SNOT-22 subdomain compared to control at week 24.
- LYR-210 (7500µg)-treated subjects reported decreased rhinologic, ear/facial, extra-nasal rhinologic, psychological dysfunction, and sleep dysfunction domain scores by an average of 10.0, 8.0, 5.2, 15.2, and 10.3 points from baseline, respectively.
- LYR-210 (7500µg)-treated subjects reported more than twice the minimal clinically important difference in each SNOT-22 subdomain at week 24.

These results are supportive of the previously reported, statistically significant 19-point improvement for LYR-210 (7500µg) over control in SNOT-22 total score at week 24.

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

The 36-item short-form health survey, version 2 (SF-36v2) is a validated, non-disease specific, and frequently used patient-reported outcome instrument to measure physical and mental health in clinical trials.

Key results include:

- LYR-210 (7500µg)-treated subjects reported a statistically significant improvement at week 24 in the Mental Component Summary, vitality, social functioning, role-emotional, and mental health scores compared to control.
- LYR-210 (7500µg)-treated subjects reported statistically significant improvement at week 24 in the physical functioning, role-physical, and bodily pain scores, compared to control.
- At week 24, the mean change from baseline for LYR-210 (7500µg)-treated subjects met the threshold for clinical meaningfulness compared to control in the Mental Component Summary and all individual scales except general health.

These data suggest that LYR-210 (7500µg) may improve the mental and physical health and quality of life of CRS patients.

About LANTERN Phase 2 Study

Surgically naïve adults with moderate-to-severe CRS who failed previous medical management enrolled in a multicenter, randomized (1:1:1), controlled LANTERN study. Patients received either bilateral administration of LYR-210 (2500µg) (n=23) or LYR-210 (7500µg) (n=21), or sham-procedure control (n=23). Both LYR-210 doses were safe and well-tolerated over the 24-week treatment period. LYR-210 (7500µg)-treated subjects demonstrated rapid, durable, dose-dependent, global symptom improvement, over 6 months from a single administration.

About LYR-210

LYR-210 is an investigational product candidate that utilizes Lyra's proprietary XTreo™ platform to enable six months of local, intra-nasal, anti-inflammatory therapy from a single treatment for chronic rhinosinusitis (CRS). LYR-210 is designed as a non-invasive alternative to sinus surgery for the millions of CRS patients who have failed medical management. LYR-210 is a bioresorbable polymeric matrix designed to be administered in a brief in-office procedure and is intended to deliver up to six months of continuous mometasone furoate (MF) drug therapy to the sinonasal passages. In the LANTERN Phase 2 study, LYR-210 (7500 µg) demonstrated rapid, clinically meaningful and durable symptom improvement in a composite score of CRS cardinal symptoms over six months. These results were supported in the Phase 2 LANTERN 6-month post treatment evaluation which showed a durable response in about 50% of treated CRS patients six months post LYR-210 removal. A pharmacokinetic (PK) study showed that MF blood levels were constant over the 56-day treatment period, confirming that LYR-210 delivers a steady daily dose of MF with accompanying rapid symptom relief during this time period. There are approximately 14 million patients with CRS in the US, approximately four million of whom fail current standard of care medical management.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, local delivery of medications to diseased tissues not accessible with conventional therapeutic approaches. Lyra's XTreo™ platform is comprised of a biocompatible mesh scaffold, an engineered elastomeric matrix and a versatile polymer-drug complex. The company's current pipeline of therapeutics target tissues deep in the ear, nose and throat passages and is designed to deliver continuous drug therapy for up to six months following a single non-invasive, in-office administration. Lyra has two product candidates in late-stage development for CRS, a highly prevalent inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities: LYR-210, for surgically naïve patients is being evaluated in the ENLIGHTEN Phase 3 clinical program, and LYR-220, is being evaluated in patients who have recurrent symptoms despite surgery in the BEACON Phase 2 clinical study. These two product candidates are designed to treat the estimated four million CRS patients in the U.S. that fail medical management each year. For more information, please visit www.lyratherapeutics.com and follow us on [LinkedIn](#) and [Twitter](#).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the presentation at COSM, LYR-210 and the potential for it to transform the treatment paradigm for CRS patients and meaningful improve the mental and physical health and quality of life of CRS patients, the advancement of LYR-210 through the clinic in the ENLIGHTEN Phase 3 Program, our pipeline of product candidates, and the progress and timing of clinical trials, and the anticipated success of leveraging the XTreo™ platform. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the fact that the company has incurred significant losses since inception and expects to incur losses for the foreseeable future; the company's need for additional funding, which may not be available; the company's limited operating history; the fact that the company has no approved products; the fact that the company's product candidates are in various stages of development; or the fact that the company may not be successful in its efforts to identify and successfully commercialize its product candidates; the fact that clinical trials required for the company's product candidates are expensive and time-consuming, and their outcome is uncertain; the fact that the FDA may not conclude that certain of the company's product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway; the company's inability to obtain required regulatory approvals; effects of recently enacted and future legislation; the possibility of system failures or security breaches; effects of significant competition; the fact that the successful commercialization of the company's product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies; failure to achieve market acceptance; product liability lawsuits; the fact that the company relies on third parties for the manufacture of materials for its research programs, pre-clinical studies and clinical trials; the company's reliance on third parties to conduct its preclinical studies and clinical trials; the company's inability to succeed in establishing and maintaining collaborative relationships; the company's reliance on certain suppliers critical to its production; failure to obtain and maintain or adequately protect the company's intellectual property rights; failure to retain key personnel or to recruit qualified personnel; difficulties in managing the company's growth; effects of natural disasters; the fact that the global pandemic caused by COVID-19 could adversely impact the company's business and operations, including the company's clinical trials; the fact that the price of the company's common stock may be volatile and fluctuate substantially; significant costs and required management time as a result of operating as a public company and any securities class action litigation. These and other important factors discussed under the caption "Risk Factors" in the company's Annual Report on Form 10-K filed with the SEC on March 9, 2022 and its other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While the company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change.

Investor Contact:

Argot Partners
212-600-1902
lyra@argotpartners.com

Media Contact:

Kathryn Morris
914-204-6412
kathryn@theyatesnetwork.com

 View original content: <https://www.prnewswire.com/news-releases/lyra-therapeutics-presents-positive-data-from-lantern-phase-2-study-of-lyr-210-for-treatment-of-chronic-rhinosinusitis-at-cosm-2022-301535997.html>

SOURCE Lyra Therapeutics, Inc.