



Lyra Therapeutics Presents Positive Full Data Set from LANTERN Phase 2 Study of LYR-210 at COSM 2021 Virtual

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New data presented includes:

- First product candidate found to be effective in non-polyp patients in addition to polyp patients in a clinical trial, based on 100% of patients in both groups achieving SNOT-22 MCID at week 24 with LYR-210 (7500µg group) -
- LYR-210 (7500µg) decreased ethmoid opacification at week 24, a measure of disease modification -
- LYR-210 (7500µg) reduced the need for rescue medication -
- Separately, Lyra also reported an analysis showing that LYR-210 (7500µg) achieved statistically significant improvement across 3 cardinal symptoms at week 24 in the LANTERN study -

WATERTOWN, Mass.--(BUSINESS WIRE)--Apr. 11, 2021-- [Lyra Therapeutics, Inc.](#) (Nasdaq: LYRA), a clinical-stage therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat (ENT) diseases, today presented data from its Phase 2 LANTERN study of LYR-210, the company's lead long-acting product candidate for chronic rhinosinusitis (CRS), at the Combined Otolaryngology Spring Meetings (COSM) 2021.

LYR-210 is an investigational product candidate designed to be administered in-office and to deliver a sustained release therapeutic for up to six months at difficult-to-access nasal inflammation sites, as a non-invasive alternative to surgery for patients who have failed medical management. Lyra reported positive topline data from the LANTERN study in December 2020.

The COSM oral presentation, titled *Long-acting implantable corticosteroid matrix for chronic rhinosinusitis: Results of LANTERN Phase 2 randomized controlled study*, contains the full 24-week data set from the company's Phase 2 clinical trial of LYR-210. Previously unpublished data included: improvement from baseline in bilateral ethmoid Zinreich scores by magnetic resonance imaging (MRI); symptom improvement in both polyp and non-polyp patients; and the need for and use of rescue medication during the trial.

"The data presented today at COSM demonstrates LYR-210's rapid and durable dose-dependent improvement based on several outcome measures, including the cardinal symptoms of CRS, SNOT-22, and MRI, in both non-polyp and polyp patients, from a single in-office administration," said Professor Anders Cervin, Garnett Passe and Rodney Williams Memorial Foundation Chair in Otolaryngology at the University of Queensland, and a Principal Investigator for Lyra's LANTERN trial. "Based on the results of the LANTERN trial, and my own experience with the drug candidate, I believe that LYR-210 has the potential to represent a major step forward in the care for CRS patients who are facing surgery as their next treatment option."

Highlights from the Oral Presentation:

- **Polyp vs Non-Polyp Patients:** Symptom improvement was observed in both polyp and non-polyp patients, with 100% of patients at the 7500µg dose in each group achieving the minimal clinically important difference (MCID) of 8.9 points for SNOT-22 total score by week 24, with a single administration of LYR-210.
- **Sinus Opacification:** In the LANTERN study, subjects underwent paranasal sinus MRI at baseline as well as at the end of treatment. LYR-210 achieved improvement in bilateral ethmoid Zinreich scores (an objective measure of sinus opacification) at week 24 in a dose-dependent manner, providing evidence of disease modification, with the 7500µg dose achieving significant improvement compared to control between the two timepoints ($p=0.031$).
- **Rescue Medication:** Only 1 patient in the 7500µg group and 2 patients in the 2500µg group required a rescue treatment compared to 7 patients in the control group over the 24-week treatment period. The first incidence of rescue treatment in the control group occurred at week 2, while the only patient to require rescue treatment in the 7500µg group did not require rescue treatment until after week 18. As such, LYR-210 (7500µg) reduced the need for rescue treatment ($p=0.048$). The need for rescue treatment in the LANTERN study was determined by the treating physician.

Separately, Lyra has shared an analysis of the LANTERN study focused on a composite of three of the cardinal symptoms of CRS.

- **Three Cardinal Symptoms:** Lyra announced an analysis of a composite score of three cardinal symptoms (3CS) of CRS, which includes nasal blockage, nasal discharge and facial pain, which are the most prevalent symptoms for surgically naïve CRS patients both with and without nasal polyps. With a single administration, LYR-210 (7500µg) achieved statistically significant improvement in the 3CS composite score compared to control at week 24 ($p=0.003$) and at earlier timepoints.

A clinical presentation of the combined data announced today is available on [Lyra's website](#).

"We are delighted to present the full data set from our LANTERN study at COSM. I believe today's data supports LYR-210's ability to provide up to 24 weeks of effective symptom relief," said Robert Kern, MD, Chief Medical Officer of Lyra Therapeutics. "LYR-210 is designed to provide continuous and consistent steroid treatment directly to diseased tissue and, additionally, eliminate patient compliance challenges. The additional data presented today shows that LYR-210 decreased ethmoid opacification and the need for rescue treatment in the LANTERN study, providing yet further evidence for

LYR-210's efficacy beyond the previously announced 4CS and SNOT-22 endpoints.”

“Our successful LANTERN study was designed to inform a pivotal Phase 3 trial for LYR-210, and today's full data set has further shaped our thoughts regarding a preferred design for that trial, subject of course to an End-of-Phase 2 meeting with the FDA,” said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. “In order to best address a combined polyp and non-polyp population, we are currently considering efficacy endpoints based on a composite 3CS of CRS score for our pivotal study, with the aim of bringing a much-needed new therapy to CRS patients as expeditiously as possible.”

About Lyra Therapeutics

[Lyra Therapeutics, Inc.](#) is a clinical-stage therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat (ENT) diseases. The company's lead product candidate, [LYR-210](#), is designed to deliver up to six months of continuous anti-inflammatory drug therapy to the sinonasal passages for the treatment of [chronic rhinosinusitis \(CRS\)](#) in patients who have not undergone surgery for the disease. Lyra is also developing LYR-220 for CRS patients who have undergone a prior surgery and have persistent disease. Beyond CRS, the company believes its [XTreo™ platform](#) comprised of drug administered through a bioresorbable polymeric matrix, has the potential to address other disease areas by precisely, consistently and locally delivering medicines for sustained periods with a single administration.

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 company's development of LYR-210 and LYR-220. 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; 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, 2021 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.

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