



## Lyra Therapeutics Announces Publication of Positive LANTERN Results in the International Forum of Allergy & Rhinology

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*LYR-210 is the First Drug-Eluting Product Candidate to Demonstrate Statistically Significant Symptom Improvement for Six Months with a Single Administration in Surgically Naïve Chronic Rhinosinusitis Patients*

*Company to Initiate Phase 3 ENLIGHTEN Program around YE'21*

WATERTOWN, Mass., Sept. 21, 2021 (GLOBE NEWSWIRE) -- 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 announced that the positive results of the Company's Phase 2 LANTERN study of LYR-210 were published online in the peer-review journal, *International Forum of Allergy & Rhinology*. The manuscript titled, "Long-acting implantable corticosteroid matrix for chronic rhinosinusitis: Results of LANTERN Phase 2 randomized controlled study," can be accessed online [here](#).

The LANTERN study evaluated the safety and efficacy of LYR-210 in surgically naïve CRS patients who had failed previous medical management. LYR-210 (7500 µg) was shown to be safe and well-tolerated over the 24-week treatment period and demonstrated statistically significant, rapid, durable, dose-dependent global symptom improvement based on composite Cardinal Symptoms (CS) scores and Sino-Nasal Outcome Test (SNOT-22).

"LYR-210 is the first and only CRS treatment candidate for surgically naïve CRS patients to demonstrate statistically significant and clinically meaningful global symptom improvement based on SNOT-22, the most widely used tool for the measurement of sinonasal symptoms, with results sustained for six months from a single, non-invasive, in-office administration," said Robert Kern, MD, Chief Medical Officer of Lyra Therapeutics. "With 4 million patients failing medical management annually, chronic rhinosinusitis is described in the literature as an 'unrecognized epidemic' due to its high prevalence, substantial impact on patient quality of life, and significant limitations of treatment options.<sup>1</sup> ENTs are eager for new options to help their CRS patients who have failed medical management but want to avoid surgery. I believe that LYR-210 has the potential to completely transform the CRS treatment paradigm."

"LYR-210 is built upon Lyra's proprietary XTreo™ platform, which delivers the right drug to the right place for the right amount of time. By delivering a consistent daily dose of the anti-inflammatory medication mometasone furoate directly to the sinonasal tissues continuously for six months, LYR-210 has shown robust CRS symptom improvement. Our upcoming Phase 3 ENLIGHTEN program will be designed to further demonstrate LYR-210's potential to provide a meaningful improvement in the lives of the millions of CRS patients, especially those without polyps who currently have no approved treatment options," said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics.

### LANTERN Study Results

The Phase 2, multicenter, blinded, randomized, controlled, dose-ranging study evaluated the safety and efficacy of LYR-210 (2500 µg) and LYR-210 (7500 µg) in 67 surgically naïve adult CRS patients who had failed previous medical management. Both LYR-210 doses were safe and well-tolerated over the 24-week treatment period. LYR-210 (7500 µg) demonstrated rapid, durable, dose-dependent, global symptom improvement, achieving statistical significance as early as 8 weeks and out to 24 weeks compared with control. Key results include:

- Rapid, durable and clinically meaningful symptom improvement by SNOT-22
  - Greater than 2-fold the MCID of 8.9 points relative to control at 24 weeks
  - 70% of patients in the 7500 µg group improved MCID at week 4; 100% by week 24
- Statistically significant improvement of composites of 3 and 4 Cardinal Symptoms (nasal blockage, facial pain/pressure, nasal discharge, olfactory loss - 4 only) at 24 weeks
- 24-week benefit from a single administration
- Showed benefit in both polyp and non-polyp patients
- Reduced rescue treatment use and radiographic ethmoid opacification at week 24

### About LYR-210 for Chronic Rhinosinusitis

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 administration 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. It is a bioresorbable polymeric matrix administered in a brief, non-invasive, in-office procedure and is intended to deliver up to six months of continuous mometasone furoate drug therapy to the sinonasal passages. In the LANTERN Phase 2 study, LYR-210 (7500mcg) demonstrated rapid, clinically meaningful and durable symptom improvement as measured by the SNOT-22 score and a cardinal symptom score over six months. There are approximately 14 million patients with CRS in the US, approximately 4 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 are designed to deliver continuous drug therapy for up to six months following a single non-invasive,

in-office administration. Lyra's lead product candidate, LYR-210, is entering Phase 3 clinical development for the treatment of chronic rhinosinusitis (CRS) as an alternative to primary sinus surgery. Lyra's second product candidate, LYR-220, is entering Phase 2 development and is designed to be an alternative to revision CRS sinus surgery and post-surgical medical management. For more information, please visit [www.lyratherapeutics.com](http://www.lyratherapeutics.com) and follow us on LinkedIn and Twitter.

### **Forward-Looking Statement**

*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 clinical advancement and efficacy of LYR-210 for the treatment of CRS and our expectations regarding the upcoming Phase 3 ENLIGHTEN program. 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; our 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 Quarterly Report on Form 10-Q filed with the SEC on August 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.*

### **Media Contact:**

Kathryn Morris  
914-204-6412  
[kathryn@theyatesnetwork.com](mailto:kathryn@theyatesnetwork.com)

### **Investor Contact:**

Argot Partners  
212-600-1902  
[lyra@argotpartners.com](mailto:lyra@argotpartners.com)

<sup>1</sup> Tan BK, Kern RC, Schleimer RP, Schwartz BS. Chronic rhinosinusitis: the unrecognized epidemic. *Am J Respir Crit Care Med.* 2013; **188**: 1275- 1277.