Lyra Therapeutics Announces Additional Data Presentations from Phase 2 LANTERN Study at the American Rhinologic Society Annual Meeting

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Significantly more patients with moderate/severe symptoms of chronic rhinosinusitis at baseline improved to mild/no symptoms at week 24 after treatment with LYR-210 (7500µg) compared to control

The three cardinal symptoms composite score shown to correlate with the well-established SNOT-22 scores at week 24 in the LANTERN study

WATERTOWN, Mass., Sept. 10, 2022 /PRNewswire/ -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) (the Company or 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, announced that new LYR-210 data analyses from the Phase 2 LANTERN study will be presented today at the 68th Annual Meeting of the American Rhinologic Society (ARS) in Philadelphia.

The additional results from the previously-reported Phase 2 LANTERN study showed that LYR-210 (7500µg) significantly improved symptom severity from baseline of 3 cardinal symptoms (3CS) of chronic rhinosinusitis (CRS) – nasal blockage, nasal discharge, and facial pain/pressure – when assessed in a responder analysis as individual and composite symptom scores at week 24. Compared to control, significantly higher proportions of LYR-210-treated subjects improved from moderate or severe at baseline to mild or none at week 24 in nasal blockage, nasal discharge, and facial pain/pressure ($p<0.05$). Consistent with other reported data from the LANTERN study, LYR-210 demonstrated a dose-dependent response in the 3CS severity analysis.

"This new LANTERN data provides additional evidence of the potential for LYR-210 to offer meaningful improvement of patients' CRS symptoms and quality of life," said Brent A. Senior, MD, Department of Otolaryngology – Head & Neck Surgery, University of North Carolina at Chapel Hill, and chair of the data monitoring committee for the LANTERN study who will present the LYR-210 data at ARS. "The data supports the use of the 3 cardinal symptoms (3CS) score for assessing CRS patients' symptoms, augmenting the assessment tools available in addition to SNOT-22 to guide the treatment of CRS. Consistently across all measures, LYR-210 achieved significant improvement in symptom severity and shows promise as a potential new treatment option for CRS patients who still experience debilitating symptoms with current treatment approaches."

A second oral presentation for LYR-210 at the ARS meeting will highlight the correlation between the 3CS composite scores and Sino-Nasal Outcome Test (SNOT-22) scores. The data show that the clinical changes in CRS patients measured in the 3CS composite score strongly and significantly correlate with the change in SNOT-22 total score, based on data evaluated at week 24 in the LANTERN study. Both assessments, 3CS and SNOT-22, provide critical information on a patient's response to treatment and the impact CRS has on quality of life.

"We are enthusiastic to share these results for LYR-210 with the ENT treatment community at the ARS meeting. LYR-210 is the first product candidate designed to provide six months of therapy with a single treatment for CRS patients," said Richard Nieman, M.D., Chief Medical Officer of Lyra Therapeutics. "We continue to advance LYR-210 in the ongoing ENLIGHTEN Phase 3 program as a potential new treatment for patients."

The presentations of the data announced today are available on Lyra's website.

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 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 (7500µg) demonstrated clinically meaningful, rapid, durable, dose-dependent symptom improvement over 24 weeks compared with control, based on composite Cardinal Symptoms (CS) scores and Sino-Nasal Outcome Test (SNOT-22). 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 Chronic Rhinosinusitis (CRS)

CRS is a highly prevalent inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities and is the fifth most common condition in people under 65. Cardinal symptoms include nasal obstruction and congestion, facial pain and pressure, nasal discharge, and olfactory loss. The prevalence of CRS in the U.S. is estimated to be 14 million, with 8 million treated annually using medical management including topical steroid sprays and oral steroids. Roughly half of those treated fail and seek alternative medical intervention. While ENT

physicians perform approximately 400,000 surgeries annually for CRS, 65% of patients have recurrent symptoms and 100% require ongoing medical management. Additionally, many patients are surgery unwilling as the current procedures are invasive, not curative, and often require long recovery times.

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 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, for patients who have recurrent symptoms despite surgery, is being evaluated in the BEACON Phase 2 clinical trial. 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 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 date and details of the presentations at ARS, our pipeline of product candidates, the success of the XTreo™ platform, and the success and efficacy of LYR-210. 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 additional 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, terrorism and wars (including the developing conflict between Ukraine and Russia); 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 Securities and Exchange Commission (SEC) on August 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.

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