Lyra Therapeutics Announces Initiation of LYR-210 Pivotal Phase 3 ENLIGHTEN Program in Surgically Naïve Chronic Rhinosinusitis Patients

January 24, 2022

Company also announces initiation of BEACON clinical study of LYR-220 in previously operated chronic rhinosinusitis patients

LYR-210 and LYR-220 are designed to complement each other in addressing the broad spectrum of CRS patients treated by ENT Physicians

WATERTOWN, Mass., Jan. 24, 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 announced the initiation of the Phase 3 ENLIGHTEN I clinical trial of LYR-210 in adult, surgically naïve chronic rhinosinusitis (CRS) patients, with trial sites open for enrollment. LYR-210 is designed to be administered in a brief, non-invasive, in-office procedure and deliver up to six months of continuous anti-inflammatory medication to the sinonasal passages.

"LYR-210 is the first product candidate designed to provide six months of continuous therapy with a single treatment and represents a significant opportunity to introduce a new standard of care to the millions of CRS patients suffering with the disease and seeking a non-surgical treatment that provides significant symptom relief," said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics. "Following the positive results achieved in the LANTERN Phase 2 study of LYR-210 demonstrating rapid, durable, and clinically meaningful improvement, we look forward to advancing our Phase 3 ENLIGHTEN pivotal program with the initiation of ENLIGHTEN I, followed by initiation of ENLIGHTEN II, the second Phase 3 study, within the first half of this year."

ENLIGHTEN I is a Phase 3 multicenter, randomized, controlled trial to evaluate the efficacy and safety of LYR-210 compared to control. The trial will enroll approximately 180 CRS patients who have failed medical management and have not had a prior sinus surgery, randomized 2:1 to receive either LYR-210 (7500µg MF) or control. The primary endpoint of the trial is the change from baseline in a composite score of three cardinal symptoms (3CS) of CRS (i.e., nasal blockage, nasal discharge, and facial pain) at week 24. Enrollment is anticipated to be completed in the first half of 2023. After the 24-week treatment duration, control patients in ENLIGHTEN I will be eligible to crossover into treatment as part of an extension study that will also include repeat administration with LYR-210 in previously treated patients. ENLIGHTEN I is the first of two pivotal trials the company will be conducting to support the NDA for LYR-210.

For the Company's second product candidate, LYR-220 for the treatment of adult patients with CRS who have had a prior surgery for their CRS symptoms, the BEACON Phase 2 trial has been initiated. The BEACON trial is a controlled, randomized, parallel-group study to evaluate safety, tolerability, pharmacokinetics, and efficacy comparing 2 designs of LYR-220 to control over a 24-week period in approximately 70 symptomatic adult CRS subjects who have had a prior bilateral sinus surgery. Enrollment is anticipated to be completed around the end of 2022.

"As a practicing rhinologist, I am very optimistic that these product candidates will provide meaningful improvement for the millions of CRS sufferers who currently have no approved therapy and am encouraged to see the forward progress of these product candidates through clinical development. I believe these innovative treatments have the potential to transform the current treatment paradigm for the broad spectrum of CRS patients who have failed first line medical management," said Robert Kern, MD, Chief Medical Officer of Lyra Therapeutics.

About LYR-210 & LYR-220

LYR-210 and LYR-220 are investigational product candidates that utilize Lyra's proprietary XTreo^{TM} platform to enable six months of local, intra-nasal, anti-inflammatory therapy from a single treatment for chronic rhinosinusitis (CRS). Both product candidates are bioresorbable polymeric matrices designed to be administered in a brief, non-invasive, in-office procedure and are intended to deliver up to six months of continuous mometasone furoate drug therapy to the sinonasal passages as a non-invasive alternative to sinus surgery. LYR-210 is designed for surgically naïve patients, while LYR-220, an enlarged matrix, is intended for use in patients with post-surgical anatomy. Together, the two products are designed to address the four million CRS patients who fail medical management annually. In the LANTERN Phase 2 study, LYR-210 (7500 µg) demonstrated rapid, clinically meaningful and durable symptom improvement in CRS three cardinal symptoms (3CS) over six months. A pharmacokinetic (PK) study showed that Mometasone Furoate (MF) blood levels were constant over the 56 days, confirming that LYR-210 delivers a steady daily dose of MF with accompanying rapid symptom relief during this time period. Clinical data from LYR-210 trials may be included in LYR-220's regulatory submission. There are approximately 14 million patients with CRS in the US, with no approved treatments for roughly 90% of the CRS population.

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 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, and LYR-220, for patients who have recurrent symptoms despite surgery. Together they 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 enrollment of the Phase 3 ENLIGHTEN I clinical trial for LYR-210 and anticipated completion of enrollment in mid-2023; crossover of control patients in ENLIGHTEN I into treatment as part of an extension study; initiation of ENLIGHTEN II, the second Phase 3 study within the first half of 2022; completion of enrollment for the BEACON Phase II trial for LYR-220 around the end of 2022; and the success of Lyra's product candidates. 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 Quarterly Report on Form 10-Q filed with the SEC on November 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.

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-announces-initiation-of-lyr-210-pivotal-phase-3-enlighten-program-in-surgically-naive-chronic-rhinosinusitis-patients-301466254.html

SOURCE Lyra Therapeutics, Inc.