Lyra Therapeutics Announces First Patient Enrolled in Pivotal ENLIGHTEN II Clinical Trial of LYR-210 in Chronic Rhinosinusitis Patients

September 8, 2022

ENLIGHTEN II is the second of two Phase 3 trials enrolling surgically-naïve CRS patients in the Global ENLIGHTEN clinical program.

WATERTOWN, Mass., Sept. 8, 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, today announced the enrollment of the first patient in the Phase 3 ENLIGHTEN II clinical trial of LYR-210 in adult patients with chronic rhinosinusitis (CRS). LYR-210 is designed as an alternative to sinus surgery for the millions of CRS patients that remain symptomatic despite treatment.

ENLIGHTEN II is the second Phase 3 trial in the pivotal clinical program for LYR-210, along with the ENLIGHTEN I trial that was initiated earlier this year. The two ENLIGHTEN trials will enroll surgically-naïve CRS patients in the U.S. and Europe to support a New Drug Application to the U.S. Food and Drug Administration for LYR-210.

"We are excited about the ENLIGHTEN pivotal program, with both Phase 3 trials now actively enrolling patients," said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. "LYR-210 is the first CRS product candidate designed to provide six months of continuous therapy with a single treatment, and we are focused on the opportunity to bring a new standard of care to the millions of CRS patients suffering with the disease."

The ENLIGHTEN program consists of two Phase 3 studies expected to include a total of 360 adult, surgically-naïve CRS patients. ENLIGHTEN II is a multicenter, randomized, controlled trial to evaluate the efficacy and safety of LYR-210 (7500µg MF) compared to control. The trial will enroll approximately 180 CRS patients who have failed medical management and have not had prior sinus surgery, randomized 2:1 to 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.

"I am very happy that the first patient has now been enrolled at our site in this important trial," said Dr. Adil Fatakia, M.D., Tandem Clinical Research in Marrero, LA. "My Investigator colleagues at other sites in the U.S. and around the world look forward to enrolling this trial to allow the required data to be collected, which will support submission of this program for approval."

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 (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 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 enrollment and success of the Phase 3 ENLIGHTEN program; the timing for topline results from the Phase 3 ENLIGHTEN program; 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 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.

Contact:
Kathryn Morris
The Yates Network LLC
914-204-6412
kathryn@theyatesnetwork.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/lyra-therapeutics-announces-first-patient-enrolled-in-pivotal-enlighten-ii-clinical-trial-of-lyr-210-in-chronic-rhinosinusitis-patients-301620102.html

SOURCE Lyra Therapeutics, Inc.