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

February 28, 2022

WATERTOWN, Mass., Feb. 28, 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 enrollment of the first patient in the Phase 3 ENLIGHTEN I 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.

"Millions of CRS patients continue to experience debilitating symptoms despite having used conventional medical management, including topical nasal steroid sprays and oral steroids. We have limited, non-invasive options to offer to these patients," said Randall Ow, MD, FACS, FARS, FAAOA, FAPCR, of Sacramento Ear Nose & Throat, and an investigator in the ENLIGHTEN I study of LYR-210. "LYR-210 may represent a promising new, non-invasive treatment option for CRS patients who fail medical management. LYR-210 is convenient to implant in a routine office visit and seamlessly conforms to the patient's nasal anatomy, enabling continuous anti-inflammatory treatment for up to six months with one administration."

The ENLIGHTEN program will consist of two, staggered Phase 3 studies totaling 360 patients. ENLIGHTEN I is a 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 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. After the 24-week treatment stage, control patients in ENLIGHTEN I will be eligible to receive LYR-210 (7500µg MF) crossover treatment as part of an extension study that will also include repeat administration of LYR-210 (7500µg MF) in a portion of patients previously randomized to the treatment arm. The second Phase 3 trial, ENLIGHTEN II is anticipated to commence mid-year 2022. Together, the aim of the two pivotal trials is to support an anticipated New Drug Application to the U.S. Food and Drug Administration for LYR-210.

"LYR-210 could represent a meaningful advance in the care of patients who suffer from persistent burdensome symptoms due to limited, ineffective treatment options," said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics. "LYR-210 represents a significant opportunity to introduce a new standard of care to the millions of patients who seek an alternative to sinus surgery."

Palasis continued, "With our two product development candidates — LYR-210 for surgically-naïve patients, and LYR-220 for patients who remain symptomatic despite surgery — Lyra is poised to address the four million CRS patients who failed medical management annually."

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 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. LYR-210 is a bioresorbable polymeric matrix designed to be administered in a brief, non-invasive, 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 CRS three cardinal symptoms (3CS) 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 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 naive patients, and LYR-220 for patients who have recurrent symptoms despite surgery, 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 the enrollment and timeline for the Phase 3 ENLIGHTEN clinicals trials of LYR-210 in adult patients with CRS and the 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 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 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 to download multimedia:https://www.prnewswire.com/news-releases/lyra-therapeutics-announces-first-patient-dosed-in-pivotal-enlighten-i-clinical-trial-of-lyr-210-in-chronic-rhinosinusitis-patients-301491152.html

SOURCE Lyra Therapeutics, Inc.