Lyra Therapeutics Fully Enrolls Pivotal Phase 3 ENLIGHTEN I Trial of LYR-210 for the Treatment of Chronic Rhinosinusitis

August 29, 2023

Topline Results Expected 1H 2024

WATERTOWN, Mass., Aug. 29, 2023 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), a clinical-stage biotechnology company developing long-acting anti-inflammatory therapies for the localized treatment of chronic rhinosinusitis (CRS), today announced that the pivotal Phase 3 ENLIGHTEN I clinical trial of LYR-210 in adult patients with CRS who have not had prior ethmoid sinus surgery, is fully enrolled. LYR-210 is a bioresorbable nasal implant designed to deliver six months of continuous anti-inflammatory medication (mometasone furoate; MF) to the sinonasal passages for the treatment of CRS. Topline results from ENLIGHTEN I are expected in the first half of 2024 as planned.

"We are pleased to have fully enrolled the first of our two pivotal trials of LYR-210 in CRS patients," said Richard Nieman, MD, Chief Medical Officer of Lyra Therapeutics. "Our clinical team is now focusing all of its recruitment efforts on the second of our two pivotal trials, ENLIGHTEN II, for which we expect to complete enrollment in the second half of 2024," Dr. Nieman continued. "We thank the participants and the investigators in the ENLIGHTEN studies as we advance our technology that could potentially benefit millions of patients with CRS."

About the ENLIGHTEN Pivotal Program

The ENLIGHTEN program consists of two pivotal Phase 3 clinical trials, ENLIGHTEN I and ENLIGHTEN II, to evaluate the efficacy and safety of LYR-210 for the treatment of CRS. Each ENLIGHTEN trial is enrolling 180 CRS patients who have failed medical management and have not had prior ethmoid sinus surgery, randomized 2:1 to either LYR-210 (7500µg mometasone furoate (MF)) or sham control for 24 weeks. The two pivotal trials will support a New Drug Application to the U.S. Food and Drug Administration for LYR-210. Lyra has manufactured clinical supply of LYR-210 in house for both ENLIGHTEN trials.

About LYR-210

LYR-210 is an investigational product candidate for the treatment of chronic rhinosinusitis (CRS) in patients who have failed current therapies and require further intervention. LYR-210 is a bioresorbable nasal implant designed to be inserted in a simple, in-office procedure. LYR-210 is intended to deliver six months of continuous anti-inflammatory therapy, mometasone furoate, to the sinonasal passages to treat CRS. In the LANTERN Phase 2 randomized, controlled trial of LYR-210 for the treatment of CRS, LYR-210 achieved rapid and durable improvements in the SinoNasal Outcome Test (SNOT-22) score over 24 weeks. No treatment-related Serious Adverse Events (SAEs) were observed. LYR-210 is being evaluated in the ENLIGHTEN Phase 3 pivotal clinical program.

About Lyra Therapeutics
Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing long-acting anti- inflammatory therapies for the localized treatment of patients with chronic rhinosinusitis (CRS). Lyra has two investigational product candidates, LYR-210 and LYR-220, 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 and LYR-220 are bioresorbable nasal implants designed to be inserted in a simple, in-office procedure and are intended to deliver six months of continuous mometasone furoate drug therapy (7500µg MF) to the sinonasal passages. LYR-210 is designed for surgically naïve patients and is being evaluated in the ENLIGHTEN Phase 3 clinical program, while LYR-220, an enlarged implant, is being evaluated in the BEACON Phase 2 clinical trial in patients who have recurrent symptoms despite prior ethmoid sinus surgery. These two product candidates are designed to treat the estimated four million CRS patients in the United States who fail medical management each year. For more information, please visit www.lyratx.com and follow us on LinkedIn.

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 completion of the Company's second Phase 3 clinical trial, and the release of data from both of the Company's Phase 3 clinical trials. 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. 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 8, 2023 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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