Lyra Therapeutics Fully Enrolls Pivotal Phase 3 ENLIGHTEN 2 Trial of LYR-210 for the Treatment of Chronic Rhinosinusitis

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-- Topline Results Expected Q2 2025 --

WATERTOWN, Mass., Oct. 15, 2024 (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 2 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) to the sinonasal passages for the treatment of CRS. Topline results from ENLIGHTEN 2 are expected in Q2 2025.

"We are pleased to have fully enrolled the second of our two pivotal trials of LYR-210 in CRS patients, and our team is moving forward expeditiously to report the results in Q2 of next year," said Maria Palasis, Ph.D., President and CEO of Lyra Therapeutics. "We thank the participants and the investigators in the ENLIGHTEN studies who have enabled the evaluation of our technology that could potentially benefit patients with CRS."

About the ENLIGHTEN Pivotal Program

The ENLIGHTEN program consists of two pivotal Phase 3 clinical trials, ENLIGHTEN 1 and ENLIGHTEN 2, to evaluate the efficacy and safety of LYR-210 for the treatment of CRS. Each ENLIGHTEN trial has enrolled approximately 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) or sham control for 24 weeks.

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. LYR-210 is being evaluated in the ENLIGHTEN pivotal Phase 3 clinical program.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing long-acting, anti-inflammatory sinonasal implants for the treatment of chronic rhinosinusitis (CRS). Lyra Therapeutics is developing therapies for CRS, a highly prevalent inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities. LYR-210, the company's lead product, is a bioabsorbable nasal implant designed to be administered in a simple, in-office procedure and is intended to deliver six months of continuous anti-inflammatory drug therapy (7500µg mometasone furoate) to the sinonasal passages for the treatment of CRS with a single administration. LYR-210, being evaluated in the ENLIGHTEN Phase 3 clinical program, is intended for patients with standard anatomy, primarily patients who have not undergone ethmoid sinus surgery. The company's therapies are intended 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 whether LYR-210 could potentially benefit patients with CRS, the completion of the Company's ENLIGHTEN 2 Phase 3 clinical trial, and the timing of the release of topline data from the ENLIGHTEN 2 Phase 3 clinical trial. 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 14, 2024 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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