Lyra Therapeutics Announces Restart of Pivotal Phase 3 ENLIGHTEN II Clinical Trial of LYR-210 in Chronic Rhinosinusitis

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WATERTOWN, Mass., April 25, 2023 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), a clinical-stage biotechnology company developing innovative therapies for the localized treatment of chronic rhinosinusitis (CRS), today announced that it has resumed screening and enrollment in ENLIGHTEN II, its second pivotal Phase 3 clinical trial of LYR-210 in patients with CRS. LYR-210 is a bioresorbable nasal implant designed as an alternative to sinus surgery for the millions of CRS patients who remain symptomatic despite treatment.

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. Enrollment in the ENLIGHTEN I clinical trial remains on track, with pivotal data anticipated in 1H 2024. Lyra announced in November 2022 that it temporarily paused enrollment in ENLIGHTEN II due to a transition to in-house manufacturing to ensure consistent clinical supply of LYR-210. The Company expects to complete enrollment in the ENLIGHTEN II trial in the second half of 2024. Lyra is manufacturing LYR-210 in house for both ENLIGHTEN trials.

"Our in-house manufacturing team was able to expedite the increased production of LYR-210 to allow us to resume enrollment in ENLIGHTEN II ahead of our original expectation of third quarter of 2023," said Maria Palasis, Ph.D., President and CEO of Lyra. "We believe that Lyra's internal manufacturing capabilities and quality systems will continue to strengthen our ability to expedite our promising candidates toward approval and commercialization, while reducing regulatory risk and risks associated with technology transfer to third parties."

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 control. Together, the two pivotal trials are expected to support an anticipated New Drug Application to the U.S. Food and Drug Administration for LYR-210.

About LYR-210

LYR-210 is an investigational product candidate for use in chronic rhinosinusitis (CRS) patients who have failed current treatments and require further intervention. LYR-210 is a bioresorbable nasal implant administered in a brief in-office procedure. LYR-210 is intended to deliver up to six months of continuous, proven 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 improvement 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 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 administered in a brief, 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 having had 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 Company's cash runway through mid-2024, the Company's pipeline of product candidates, the enrollment and success of the ENLIGHTEN Phase 3 program, the timing for reporting top line data from the Company's clinical trials, the Company's ability to manufacture its product candidates, and the success of the Phase 2 BEACON 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, 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; the fact that the Company has never scaled up a manufacturing facility for commercial use; 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 must scale its in-house manufacturing capabilities or rely 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 Annual Report on Form 10-K filed with the SEC on March 29, 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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