Lyra Therapeutics Announces Completion of Enrollment in the BEACON Phase 2 Clinical Trial of LYR-220 in Post-Surgical Chronic Rhinosinusitis Patients

February 6, 2023

-- Topline Results Expected in Q4 2023 --

-- LYR-220 is Lyra's Second Product Candidate, Following LYR-210 in Surgically-Naïve CRS patients --

WATERTOWN, Mass., Feb. 06, 2023 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) (the Company or Lyra), a clinical-stage biotechnology company developing innovative therapies for the localized treatment of chronic rhinosinusitis (CRS), today announced completion of enrollment in the Phase 2 BEACON clinical trial of LYR-220 in adult patients with CRS who have had prior sinus surgery. LYR-220 is designed to deliver six months of continuous anti-inflammatory medication (mometasone furoate; MF) to the sinonasal passages for the treatment of CRS. Topline results are expected in the fourth quarter of 2023.

"We are pleased to have fully enrolled the BEACON trial, building on the success of Part 1 of the study which provided encouraging preliminary efficacy improvements in SNOT-22 scores as early as six weeks," said Richard Nieman, M.D., Chief Medical Officer of Lyra. "Our momentum with the LYR-220 program in post-surgical CRS patients adds to our continued progress with LYR-210, which is in pivotal Phase 3 trials for surgically-naïve CRS patients. These two development programs position Lyra to offer solutions for the full spectrum of CRS patients and their ENT physicians."

The Phase 2 BEACON trial is a sham-controlled, parallel-group study to evaluate safety and efficacy of the LYR-220 (7500µg MF) matrix, over a 24-week period, in symptomatic adult CRS patients who have had a prior bilateral ethmoid sinus surgery. The trial consists of two parts: Part 1 was designed primarily to assess the feasibility and tolerability of two 7500µg MF matrix designs; in Part 2, 40 patients have been randomized 1:1 to receive LYR-220 or sham control.

In September 2022, Lyra announced positive initial data from the Part 1, non-randomized portion of the BEACON trial, demonstrating the feasibility and tolerability of LYR-220 placement bilaterally in this patient population. All six patients were treated for at least six weeks and no serious or unexpected product-related adverse events were reported. Although efficacy evaluation was not the objective in the uncontrolled Part 1 stage of the trial, there was a mean improvement of 21 points (37%) from baseline in the 22-item Sino-nasal Outcome Test (SNOT-22) total score at six weeks. This is greater than twice the minimal clinically important difference of 8.9 points.[1]

About LYR-220

LYR-220 is an investigational product candidate for use in CRS patients who continue to require treatment to manage CRS symptoms despite having had prior ethmoid sinus surgery, a population which represents approximately forty percent of the four million CRS patients who fail medical management annually. LYR-220 is a bioresorbable, polymetric matrix that is designed to deliver six months of continuous anti-inflammatory medication (7500µg MF) to the sinonasal passages for the treatment of CRS.

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 polymeric matrices 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 matrix, is being evaluated in the BEACON Phase 2 clinical trial in patients who have recurrent symptoms despite 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.lyratherapeutics.com.

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 pipeline of product candidates, the enrollment and success of the ENLIGHTEN Phase 3 program, and the enrollment and 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; 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 Quarterly Report on Form 10-Q filed with the SEC on November 8, 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.

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[1] *Int Forum Allergy Rhinol*. 2017 Dec; 7(12): 1149–1155.