Lyra Therapeutics Announces Positive Topline Results from BEACON Phase 2 Study of LYR-220 for the Treatment of Chronic Rhinosinusitis (CRS) in Patients with Prior Ethmoid Sinus Surgery

September 12, 2023

Study demonstrates statistically significant and clinically relevant improvements in 3 Cardinal Symptoms and SNOT-22 scores at 24 weeks

Statistically significant improvements in efficacy were observed as early as 2 weeks

Primary endpoint met with no serious adverse events observed

LYR-220, Lyra's second product candidate, is a long-acting anti-inflammatory therapy in development for CRS patients with and without polyps who have recurrent symptoms despite prior ethmoid sinus surgery

Conference call today at 8:00 a.m. ET.

WATERTOWN, Mass., Sept. 12, 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 positive topline results from the BEACON Phase 2 clinical study of LYR-220 in adult patients with CRS, with and without polyps, who have had prior ethmoid sinus surgery. The study met its primary safety endpoint, with no serious adverse events observed. Most commonly reported adverse events included sinusitis, nasopharyngitis, bronchitis, and COVID-19.

LYR-220 significantly improved important patient reported outcome measures compared to sham control:

- Statistically significant improvement in a composite of the 3 cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain/pressure) at week 24 (-1.50; p=0.02)
- Statistically significant improvements in Sino-Nasal Outcome Test (SNOT-22) score compared to sham control at week 24 (-16.8; p=0.007)
- Statistically significant improvement in a composite of the 3 cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain/pressure) as early as week 4 (-0.87; p=0.037)
- Statistically significant improvements in SNOT-22 were observed as early as week 2 (-9.0; p=0.031)
- Improvements in SNOT-22 were sustained throughout the study and clinically meaningful with almost twice the minimal clinically important difference observed at week 24 compared to sham (-16.8 points)

LYR-220 is a bioresorbable nasal matrix 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 the BEACON study of LYR-220 will be presented at the American Rhinologic Society (ARS) 69th Annual Meeting on September 30, 2023, in Nashville, TN. Full results will be submitted for future publication.

"We are thrilled with these results in patients with recurrent symptoms following sinus surgery demonstrating statistically significant improvements in 3CS and SNOT-22 scores, both important efficacy outcomes," said Richard Nieman, M.D., Chief Medical Officer of Lyra Therapeutics. "We look forward to presenting the results from the BEACON study at the ARS meeting later this month."

"We believe the results achieved with LYR-220 in this patient population demonstrate the broad potential of Lyra's technology to offer meaningful clinical benefit across the spectrum of CRS patients," said Maria Palasis, Ph.D., President and CEO, Lyra Therapeutics. "These results provide additional confidence in the ongoing ENLIGHTEN pivotal Phase 3 program of LYR-210 in pre-surgical CRS patients, for which we anticipate topline data will be available in the first half of 2024."

"The BEACON study results are very promising, demonstrating significant, long-lasting improvements in patient outcomes with a simple, in-office procedure," said Brent A. Senior, MD, Harold C. Pillsbury, III Distinguished Professor and Chief of Division of Rhinology, Allergy, and Endoscopic Skull Base Surgery in the Department of Otolaryngology/Head and Neck Surgery, UNC School of Medicine and Coordinating Investigator for the BEACON study. "If confirmed in Phase 3, these results suggest that Lyra's technology has the potential to offer ENT physicians a new treatment option to improve symptoms and quality of life for CRS patients."

Conference Call and Webcast

Lyra will host a conference call and webcast on Tuesday, September 12 at 8:00 a.m. ET to discuss the topline results of the BEACON study.

To listen online via webcast, please visit: https://edge.media-server.com/mmc/p/xfx5b2kt. The webcast and accompanying slides will be archived and available at https://investors.lyratherapeutics.com.

To participate in the conference call by telephone, please register using this online form: https://register.vevent.com/register/BI5027ff27ec2f477cb5cdb98957d840d2.

BEACON Data Presentation at American Rhinologic Society (ARS) 69th Annual Meeting

Data from the BEACON Phase 2 study of LYR-220 have been selected for oral presentation at the ARS 69th Annual Meeting, taking place September 29-30, 2023 in Nashville, TN.

Title: Evaluation of LYR-220 Corticosteroid Matrices at Week 24 from the BEACON Study in CRS

Presenter: Brent A. Senior, MD, Harold C. Pillsbury, III Distinguished Professor and Chief of Division of Rhinology, Allergy, and Endoscopic Skull Base Surgery in the Department of Otolaryngology/Head and Neck Surgery, UNC School of Medicine

About the BEACON Phase 2 Clinical Study

The Phase 2 BEACON study 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 study consists of two parts: Part 1 was designed primarily to assess the feasibility and tolerability of two 7500µg MF matrix designs; in Part 2, 42 patients have been randomized 1:1 to receive LYR-220 or sham control.

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 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 nasal 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 nasal matrices designed to be administered in a simple, in-office procedure and are intended to deliver six months of continuous mometasone furoate (MF) 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 study 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.

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 and development of product candidates, including the progress, efficacy, applicability and success of LYR-220 and LYR-210; the Company's anticipated timing for the release of topline data from the ENLIGHTEN pivotal Phase 3 program of LYR-210; the date and time of the Company's conference call to discuss the topline results relating to the BEACON Phase 2 Study of LYR-220; and the Company's participation and presentation of topline results relating to the BEACON Phase 2 Study of LYR-220 at the upcoming ARS Annual Meeting. 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 an in-house manufacturing facility for clinical or 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 and commercial supply; 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 war 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 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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