Lyra Therapeutics Reports Topline Results from Phase 3 ENLIGHTEN 1 Trial for LYR-210 in Chronic Rhinosinusitis

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ENLIGHTEN 1 trial did not meet its primary endpoint

Company plans to evaluate full dataset and path forward

WATERTOWN, Mass., May 06, 2024 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), today announced topline results from the Company's Phase 3 ENLIGHTEN 1 trial evaluating LYR-210 for the treatment of chronic rhinosinusitis (CRS). ENLIGHTEN 1 did not meet its primary endpoint of demonstrating statistically significant improvement compared to sham control in the composite score of the three cardinal symptoms (3CS) of CRS (nasal obstruction, nasal discharge, facial pain/pressure) at 24 weeks. ENLIGHTEN 1 is one of two Phase 3 clinical trials evaluating LYR-210, a bioabsorbable sinonasal implant (7500µg mometasone furoate), as a six-month treatment for chronic rhinosinusitis (CRS).

"We are surprised and disappointed by the ENLIGHTEN 1 topline results," said Maria Palasis, Ph.D., President and Chief Executive Officer, Lyra Therapeutics. "We are moving as quickly as possible to evaluate the full dataset to better understand these findings in order to determine our path forward."

At 24 weeks, the ENLIGHTEN 1 trial demonstrated the following results compared to baseline, which did not achieve statistical significance:

- In the primary efficacy analysis, treatment with LYR-210 resulted in a mean (standard deviation; SD) improvement in the 3CS score of 2.13 (2.17) points, compared to 2.06 (2.14) points in sham control.
- In the intent-to-treat (ITT) population, treatment with LYR-210 resulted in a mean (SD) improvement in the 3CS score of 2.35 (2.28) points, compared to 1.89 (2.07) points in sham control.
- In the ITT population, treatment with LYR-210 resulted in a mean (SD) improvement in the Sino-Nasal Outcome Test (SNOT-22) score of 20.2 (21.38) points, compared to 15.70 (18.55) points in sham control.
- Ethmoid sinus opacification (evaluated by computed tomography (CT) scans), did not achieve statistically significant improvement after treatment with LYR-210 compared to sham control.

LYR-210 was generally well tolerated, with no product-related serious adverse events. The most commonly reported adverse events in the study population were epistaxis, nasal odor, upper respiratory tract infection and sinusitis.

The ENLIGHTEN 1 trial is ongoing and data from the 52-week extension phase are expected in Q4 2024. ENLIGHTEN 2, the second pivotal Phase 3 trial of LYR-210 in CRS, is ongoing.

The Company expects to make near-term changes to its business operations and to reduce its workforce in order to preserve cash.

About the ENLIGHTEN 1 Trial

ENLIGHTEN 1 is a randomized, blinded, sham-controlled trial designed to evaluate the efficacy and safety of LYR-210 in patients with chronic rhinosinusitis (CRS) who have failed medical management and have not had prior ethmoid sinus surgery, randomized 2:1 to either LYR-210 or sham control for 24 weeks. At the end of the treatment phase, patients in the control group receive crossover LYR-210 treatment while patients in the LYR-210 group are re-randomized 1:1 to either receive a crossover sham-procedure or a repeat treatment with LYR-210 (7500 µg mometasone furoate); all patients are then followed through 52 weeks.

ENLIGHTEN 1 enrolled a total of 190 patients, approximately two-thirds from U.S. sites and one-third from sites in Europe. The mean baseline 3CS scores were 6.9 points and 6.7 points for treatment and sham control arms, respectively, and the mean SNOT-22 scores were 61 points in both the treatment and sham control arms. The baseline CT opacification scores were 44.9% and 47.3% for the treatment and sham control arms, respectively.

About LYR-210

LYR-210 is an investigational product candidate for the treatment of chronic rhinosinusitis (CRS) for up to four million CRS patients in the U.S. who fail current therapies annually and require further intervention. LYR-210 is a bioabsorbable sinonasal implant that is designed to deliver six months of continuous anti-inflammatory medication (7500µg mometasone furoate) to the sinonasal passages for the treatment of CRS. CRS is a highly prevalent inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities and is the fifth most common condition in people under age 65.

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 has two 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 bioabsorbable nasal implants designed to be administered in a simple, in-office procedure and are 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, has a smaller dimension and is intended for patients with standard anatomy, primarily patients who have not undergone ethmoid sinus surgery. LYR-220 is a larger implant designed for CRS patients whose nasal cavity is enlarged due to previous 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. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward-looking statements. 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 our evaluation and investigation of the ENLIGHTEN 1 topline results, which will inform our path forward including our ongoing ENLIGHTEN 2 study, the timing of the full 52-week data for the ENLIGHTEN 1 study, the timing of, and the results of, the ongoing ENLIGHTEN 2 trial, the timing and scope of our near-term changes to our business operations and reduction in force in order to preserve cash, and the safety and efficacy of our product candidates. 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 ability to continue as a going concern; 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 clinical trial data is subject to change until the completion of the applicable clinical study report, 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 the Company's product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway; the Company's potential 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; 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 April 30, 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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