Lyra Therapeutics Announces Clinical Plan for LYR-210 and Late-Breaking Oral Presentation of Phase 3 ENLIGHTEN 2 Study

October 6, 2025

Company outlines clinical plan for LYR-210 based on FDA meeting on the path to NDA submission

Positive ENLIGHTEN 2 results highlighted at the AAO-HNS 2025 Annual Meeting

WATERTOWN, Mass., Oct. 06, 2025 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA), ("Lyra" or the "Company"), a late clinical-stage biotechnology company developing long-acting anti-inflammatory therapies for the localized treatment of chronic rhinosinusitis (CRS), today announced the Company's clinical plan and upcoming oral presentation of results from the positive Phase 3 ENLIGHTEN 2 trial for LYR-210, the company's lead product candidate for CRS.

Lyra plans to proceed with an additional clinical trial that was confirmed as a requirement for submission of a New Drug Application ("NDA") for LYR-210 for the treatment of CRS without nasal polyps, based on a September 2025 meeting with the U.S. Food and Drug Administration ("FDA").

"Now that we have clarity on the path forward for LYR-210, we are focused on advancing a third clinical trial in patients without nasal polyps. We plan to refine the design of this new trial based on the learnings of ENLIGHTEN 1 and ENLIGHTEN 2 and FDA feedback," said Maria Palasis, Ph.D., President and CEO, Lyra Therapeutics. "We look forward to continuing the development of LYR-210 as a six-month treatment option for millions of patients who do not respond to standard CRS medical management."

Lyra also announced a late-breaking oral presentation of the positive ENLIGHTEN 2 Phase 3 results at the Annual Meeting of the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS), taking place October 11-14 in Indianapolis.

Late-Breaking Scientific Oral Presentation

- **Title:** *LYR-210 Long-Acting Sinonasal Implants for Chronic Rhinosinusitis: Results from the Phase 3 ENLIGHTEN 2 Study*
- **Presenting Author:** Zachary M. Soler, M.D., M.Sc., Medical University of South Carolina
- **Co-Authors:** Jivianne T. Lee, M.D., Professor, UCLA School of Medicine; Robert M. Naclerio, M.D., Johns Hopkins University; Brent A. Senior, M.D., Harold C. Pillsbury, III Distinguished Professor, Department of Otolaryngology Head & Neck Surgery, University of North Caroline School of Medicine; Robert Kern, M.D., Northwestern Medical; Vineeta S. Belanger, Ph.D., SVP, Clinical Affairs, Lyra Therapeutics
- **Date and Time:** Monday, October 13 at 4:48 p.m. ET

In June 2025, Lyra announced positive results from the ENLIGHTEN 2 Phase 3 clinical trial of LYR-210 in adult patients with CRS. The ENLIGHTEN 2 trial met its primary endpoint, with LYR-210 demonstrating statistically significant improvement compared to sham control in a composite of the three cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain/pressure) at week 24 in patients without nasal polyps. The ENLIGHTEN 2 trial also met the key secondary endpoints of 3CS at 24 weeks in the full population (i.e., patients with and without nasal polyps) and in the clinically-validated SNOT-22 score at 24 weeks, with symptom improvement observed as early as week 4. Consistent with previous studies, LYR-210 was generally well-tolerated, with a safety profile similar to sham control. The 24-week endpoints in the ENLIGHTEN trials assess LYR-210's long-acting therapeutic effect as a bioresorbable sinonasal implant designed to deliver six months of continuous anti-inflammatory medication to the sinonasal passages.

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 bioabsorbable sinonasal 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 candidate, is a bioabsorbable sinonasal 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 and without nasal polyps. 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.lyra.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,” “plan”, “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 the Company’s cash runway into the third quarter of 2026, whether LYR-210 could potentially benefit patients with CRS with or without polyps, the safety, efficacy, potential benefits of, and clinical design or progress of LYR-210 at any dosage or in any indication; the in-house CMC activities to prepare for manufacturing LYR-210 for potential, future clinical trials and for compliance with applicable CMC regulations; our expectations surrounding potential regulatory submissions, progress, or approvals and timing thereof for any of our product candidates; the Company’s business strategy and plans; and the timing of any of the foregoing. 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 Company’s failure to meet its primary endpoint in its ENLIGHTEN 1 Phase 3 clinical trial; 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 clinical trial data is subject to change until the completion of the applicable clinical study report; the fact that clinical trials required for the Company’s product candidates are expensive and time-consuming, and their outcome is uncertain; effects of recently enacted and future legislation; the possibility of system failures or security breaches; effects of significant competition; the Company's reliance on third parties to conduct its preclinical studies and clinical trials; failure to obtain and maintain or adequately protect the Company's intellectual property rights; the Company’s failure to regain compliance with, or continue to meet, the listing requirements of the Nasdaq Capital Market and be delisted; the Company’s failure to retain key personnel; 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 12, 2025 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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