



Lyra Therapeutics to Present 52-week Extension Stage Results for ENLIGHTEN 1 Phase 3 Study for LYR-210 for the Treatment of Chronic Rhinosinusitis at COSM 2025

May 7, 2025

- Results from ENLIGHTEN 1 Phase 3 Extension Stage support LYR-210's favorable safety profile and general consistency with the Primary Study Phase in patients with CRS
- In the CRS patient subgroup with nasal polyps, analysis showed improvements in both symptoms and polyp size in Sham group patients that received crossover LYR-210
- Lyra continues to focus on upcoming results from ENLIGHTEN 2 pivotal Phase 3 trial in CRS patients expected in 2Q 2025

WATERTOWN, Mass., May 07, 2025 (GLOBE NEWSWIRE) -- [Lyra Therapeutics](#), Inc. (Nasdaq: LYRA), ("Lyra" or the "Company"), a clinical-stage biotechnology company developing long-acting, anti-inflammatory sinonasal implants for the treatment of chronic rhinosinusitis (CRS), today announced that the Company plans to present results from the 52-week Extension Stage of the ENLIGHTEN 1 Phase 3 study for LYR-210, the Company's lead product candidate for CRS, at the annual Combined Otolaryngology Spring Meetings (COSM 2025) being held May 14-18 in New Orleans.

The poster will present 52-week results from the Extension Stage of the ENLIGHTEN 1 study in patients with CRS, including the following highlights:

- LYR-210 was generally well tolerated and no treatment-related serious adverse events reported through Week 52.
- Repeat LYR-210 treatment demonstrated a favorable safety profile, similar to that observed in the Primary Study Stage in patients with CRS.
- Durable symptom control through 52 weeks observed after LYR-210 treatment cessation (LYR-Sham group) in both non-polyp and polyp patients.
- In non-polyp patients, despite showing a strong Sham effect in the Primary Study Stage, there was further meaningful improvement in symptoms in crossover patients that subsequently received LYR-210 in the Extension Stage.
- In the CRS patient subgroup with nasal polyps, crossover Sham-LYR group improved in both symptoms and polyp size consistent with LYR-210 treatment in the Primary Study Stage.

The poster presentation on LYR-210 is planned to take place during these poster sessions at COSM 2025:

- **Poster Title:** *LYR-210 Sinonasal Corticosteroid Implants for Chronic Rhinosinusitis: 52-week outcomes from the Phase 3 ENLIGHTEN 1 trial*
- **Location:** Elite Exhibit Hall at the Hyatt Regency New Orleans
- **Date and Time:** Poster Sessions, Fri., May 16 at 9:00 a.m.-7:00 p.m. CT and Sat., May 17 at 9:00 a.m.-4:00 p.m. CT

The ENLIGHTEN program consists of two pivotal Phase 3 clinical trials, ENLIGHTEN 1 and ENLIGHTEN 2, to evaluate the efficacy and safety of LYR-210 for the treatment of CRS. Each ENLIGHTEN trial enrolled approximately 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) or sham control for 24 weeks.

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 nasal 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, is a bioabsorbable nasal 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.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," "will," "plan," "continue," "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 timing and content of the Company's poster at COSM 2025, whether LYR-210 could potentially benefit patients with CRS, the completion of the Company's ENLIGHTEN 2 Phase 3 clinical trial, the timing of the release of data from the ENLIGHTEN 2 Phase 3 clinical trial, and whether the ENLIGHTEN results will include important data or enable the Company to gain further insight about the efficacy of LYR-210. 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 the Company terminated the employment of approximately 87 employees following the announcement that it failed to attain the primary endpoint of its ENLIGHTEN 1 Phase 3 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 fact that the Company needs to conduct at least one additional phase 3 clinical trial; 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; 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 May 6, 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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