Lyra Therapeutics Announces Positive Topline Results of Pharmacokinetic Study of LYR-210 in Patients with Chronic Rhinosinusitis

June 30, 2021

-- Results Support 505(b)(2) NDA Pathway for LYR-210

-- First U.S. Study of LYR-210 Enrolled Rapidly

WATERTOWN, Mass., June 30, 2021 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA), a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, and local delivery of medications to the ear, nose and throat (ENT) passages and other diseased tissues, today announced positive topline results from the company's pharmacokinetic (PK) study of LYR-210. Data obtained from the study are supportive of LYR-210's safety profile and provide a PK bridge to the established safety of mometasone furoate (MF) for a 505(b)(2) pathway for New Drug Approval (NDA) submission.

The clinical study was a 56-day open label, multi-center, U.S. study of the PK and safety of LYR-210 in adult subjects with chronic rhinosinusitis (CRS). The primary objective of the study was to establish the PK profile of LYR-210. The study enrolled 24 patients, half of whom received LYR-210 2500 µg and the other half received LYR-210 7500 µg. The study indicated that both doses were safe and well tolerated, with the mean maximum plasma concentration (Cmax) observed with the 7500 ug dose well below Cmax established for U.S. Food and Drug Administration-approved formulations of MF. MF blood plasma levels observed during the PK study support LYR-210's ability to deliver consistent and steady dosing over the entire treatment period. This was the first U.S. study of LYR-210 and it was fully enrolled across four sites in 11 weeks.

"The data from our PK study suggests that LYR-210 can elute mometasone furoate safely, consistently for 6 months, and locally to the inflamed mucosal tissue of CRS patients," said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics. "These results will support a 505(b)(2) pathway for LYR-210's NDA submission. We are delighted at the rapid pace of enrollment of our first U.S. patients, and believe this bodes well for interest at U.S. sites for our Phase 3 program, which we expect to initiate around the end of the year."

"LYR-210 is highly convenient to implant and explant in a routine office visit and seamlessly conforms to the patient's nasal anatomy which enables continuous treatment for up to six-months with one application," said Randall Ow, MD, FACS, FARS, FAAOA, FAPCR, of Sacramento Ear Nose & Throat, and an investigator in the PK study. "LYR-210 has the potential to address a broad patient population and could provide a meaningful treatment option to CRS patients who fail medical management."

Lyra will present the data from its PK study of LYR-210 during a podium presentation at the upcoming American Rhinologic Society Annual meeting in October 2021.

About LYR-210

LYR-210 is an investigational product candidate that utilizes Lyra's proprietary XTreo™ platform to enable six months of local, intra-nasal, anti-inflammatory therapy from a single treatment for chronic rhinosinusitis (CRS). LYR-210 is designed as a non-invasive alternative to sinus surgery for the millions of CRS patients who have failed medical management. It is a bioresorbable polymeric matrix designed to be administered in a brief, non-invasive, in-office procedure and is intended to deliver up to six months of continuous mometasone furoate drug therapy to the sinonasal passages. In the LANTERN Phase 2 study, LYR-210 (7500 µg) demonstrated rapid, clinically meaningful and durable symptom improvement in CRS three cardinal symptoms (3CS) over six months. There are approximately 14 million patients with CRS in the US, approximately 4 million of whom fail current standard of care medical management.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, local delivery of medications to diseased tissues not accessible with conventional therapeutic approaches. Lyra's XTreo™ platform is comprised of a biocompatible mesh scaffold, an engineered elastomeric matrix and a versatile polymer-drug complex. The company's current pipeline of therapeutics target tissues deep in the ear, nose and throat passages and are designed to deliver continuous drug therapy for months following a single non-invasive, in-office administration. Lyra's lead product candidate, LYR-210, is in late-stage clinical development for the treatment of chronic rhinosinusitis and is designed to deliver up to six months of continuous anti-inflammatory drug therapy to the sinonasal passages. For more information, please visit www.lyratherapeutics.com and follow us on LinkedIn and Twitter.

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 clinical advancement of LYR-210 for the treatment of CRS. 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 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 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 relies 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; 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 May 11, 2021 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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