Lyra Therapeutics Presents Clinical Data Demonstrating LYR-210's Local Anti Inflammatory Effects for the Treatment of Chronic Rhinosinusitis

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Two additional presentations highlight supporting data for LYR-210's clinical program covering key clinical endpoints for CRS and Lyra's XTreo™ drug release performance

Findings presented at the 66th Annual Meeting of the American Rhinologic Society

WATERTOWN, Mass., Sept. 10, 2020 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc., (Nasdaq: LYRA), a clinical-stage therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat (ENT) diseases, today announced the presentation of data showing that LYR-210 demonstrated a significant reduction of sinonasal Type 2 inflammation in surgically naïve patients with chronic rhinosinusitis (CRS).

The reduction of Type 2 inflammation suggests a correlation with rhinologic symptom improvement in CRS and could be a potential measure of LYR-210's local anti-inflammatory effects at the site of inflammation in the sinonasal passages. The results showing LYR-210's influence on local Type 2 inflammatory response in CRS patients are secondary findings from the company's Phase 1 clinical study of LYR-210.

"Inflammation is the key driver for symptoms of chronic rhinosinusitis, and Type 2 inflammation, in particular, has been the most resistant to treatment. These new results demonstrate that LYR-210 not only reduces local markers of Type 2 inflammation, but also reduces the associated CRS symptoms," said Robert C. Kern, MD, Chair of the Department of Otolaryngology/Head and Neck Surgery at Northwestern University Feinberg School of Medicine, Otolaryngology (Ear, Nose & Throat) Specialist with Northwestern Medical Group, and a co-author on the LYR-210 presentation. "There is a significant unmet need for new treatment options for CRS, a disease which affects the quality of life for millions of patients."

The clinical finding of LYR-210's effect on Type 2 inflammation is presented as one of three poster presentations made by Lyra and its research collaborators at the 66th Annual Meeting of the American Rhinologic Society (ARS), taking place as a virtual event this week. Lyra believes these posters support the rationale behind the company's ongoing clinical program for LYR-210.

"The findings of our 3 presentations show the promising novel features and advantages of LYR-210 across a broad range of parameters: potentially alleviating the 4 cardinal symptoms of CRS; reducing local tissue inflammation; and the ability to leverage XTreo™'s unique matrix properties of persistent tissue contact and sustained, multi-month therapeutic dosing," said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. "We are delighted to share our data, and the clinical potential of LYR-210, with the ENT community at the ARS annual meeting, especially given the near-term readout of our LANTERN Phase 2 study, for which we expect to announce top-line results at the end of this year."

Highlights of the ARS presentations include:

Poster: *A novel continuous topical steroid implant (LYR-210) reduces sinonasal type 2 inflammation and rhinologic symptoms in chronic rhinosinusitis*

- LYR-210 significantly ($p<0.05$) reduced sinonasal T2 inflammation markers IL-13, CCL26 and periostin in surgically naïve CRS patients with and without polyps. Other T2 markers, IL-5 and CCL18, showed a trend toward reduction with LYR-210.
- Protein markers for T2 inflammation were determined by Luminex, from nasal swabs collected at baseline and 4 and 12 weeks after treatment with LYR-210. RNA markers were determined by quantitative RT-PCR in RNA samples.
- The results were from the multicenter, open-label Phase 1 clinical study which administered LYR-210 to 20 patients with CRS.

Poster: *Continuous steroid delivery by LYR-210 improves symptoms of chronic rhinosinusitis*

- While the previously-reported results of the Phase 1 study of LYR-210 demonstrated significant improvement in sinonasal outcome (SNOT-22) scores measuring the overall impact of CRS on patients' quality of life, this new analysis evaluated the 4 cardinal symptoms (4CS) that define CRS, as a subset of SNOT-22.
- The 4CS of CRS are nasal blockage, post-nasal discharge, facial pain/pressure, and decreased sense of smell.
- In the Phase 1 study, the 4CS score strongly correlated with SNOT-22 in the surgically naïve CRS patients treated with LYR-210, independent of polyp status.
- As measured by both 4CS and the previously reported SNOT-22 scores, patients treated with a single administration of LYR-210 reported rapid, durable and clinically relevant improvement in CRS symptoms over the 24-week study.
- The 4CS score provides a clinically relevant assessment of the impact of a treatment on CRS symptoms.

Poster: *A drug release and pharmacokinetic evaluation of novel mometasone furoate eluting matrices*

- In this preclinical study, the bioresorbable polymeric drug matrices from the proprietary XTreo™ platform demonstrated the ability to dynamically adapt to target anatomy by conforming to the maxillary sinus cavity of the animal model.
- The XTreo™ matrices demonstrated the ability to maintain persistent tissue contact, allowing sustained local elution of the drug, mometasone furoate, to sinus tissues for up to 180 days from a single administration.

- XTreo™ drug matrices achieved persistent tissue levels of mometasone furoate throughout the multi-month dosing duration, with consistent daily dosing. Tissue and plasma MF concentrations were measured using high-performance liquid chromatography (HPLC) and liquid chromatography–tandem mass spectrometry (LC-MS/MS).

The three ARS poster presentations are available as e-posters during and after the conference, including on Lyra's website .

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat diseases. The company's proprietary technology platform, XTreo™, is designed to precisely and consistently deliver medicines directly to the affected tissue for sustained periods with a single administration. The company's initial product candidates, LYR-210 and LYR-220, are bioresorbable polymeric matrices designed to be administered in a brief, non-invasive, in-office procedure and intended to deliver up to six months of continuous drug therapy to the sinonasal passages for the treatment of chronic rhinosinusitis (CRS). The therapeutic embedded within LYR-210 and LYR-220 is mometasone furoate, which is the active ingredient in various FDA-approved drugs and has a well-established efficacy and safety profile. CRS is an inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities and affects approximately 14 million people in the United States.

The company is advancing LYR-210 as a potential preferred alternative to surgery in an ongoing Phase 2 clinical trial for CRS patients who have failed medical management. In its Phase 1 clinical trial, LYR-210 met its primary safety endpoint, and it was observed that patients generally experienced significant and rapid, clinically meaningful and durable improvement in SNOT-22 scores, an established patient symptom severity scale, through week 25, which was the end of the trial. The company is also developing LYR-220 for use in CRS patients who have an enlarged nasal cavity due to sinus surgery but continue to require treatment to manage CRS symptoms. Beyond CRS, the company believes its XTreo™ platform has potential applications in other disease areas, which it is actively exploring to further broaden the platform's therapeutic potential.

For more information, please visit www.lyratherapeutics.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. 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 lead product candidate 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 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 August 5, 2020 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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