Lyra Therapeutics Advances Phase 2 BEACON Clinical Trial of LYR-220 in Post-Surgical Chronic Rhinosinusitis Patients to Randomized Stage of Study

September 13, 2022

21-point (37%) mean improvement in SNOT-22 total score at six weeks during the uncontrolled Part 1 stage of the 24-week BEACON trial

First patient dosed in the randomized, Part 2 stage of the BEACON trial

The LYR-220 program in post-surgical patients is in addition to LYR-210 which is in phase III for surgically naïve CRS patients.

WATERTOWN, Mass., Sept. 13, 2022 /PRNewswire/ -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) (the Company or 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 that the first patients have been treated in Part 2, the randomized stage, of the Phase 2 BEACON clinical trial of LYR-220 in adult patients with chronic rhinosinusitis (CRS) who have had a prior sinus surgery. LYR-220 has been specifically designed to deliver six months of continuous anti-inflammatory medication in a controlled and consistent fashion to the sinonasal passages for the millions of CRS patients that continue to require treatment despite prior surgical treatment.

The Phase 2 BEACON trial is a sham-controlled, parallel-group study to evaluate safety, tolerability, and pharmacokinetics of LYR-220 (7500µg MF) matrix, over a 24-week period, in symptomatic adult CRS patients who have had a prior bilateral sinus surgery. Part 1 of the BEACON trial was uncontrolled and designed primarily to assess the feasibility and tolerability of two matrix designs. In the randomized Part 2 stage, one design of LYR-220 will be compared to control in approximately 40 patients.

In the Part 1 stage, six patients received the LYR-220 matrix implant, demonstrating the feasibility and tolerability of LYR-220 placement bilaterally in this patient population. All six patients were treated for at least six weeks and no serious or unexpected product related adverse events have been reported. Although efficacy evaluation is not the objective during the uncontrolled Part 1 stage of the trial, there was a mean improvement of 21 points (37%) from the baseline in the 22-item Sino-nasal Outcome Test (SNOT-22) total score at 6 weeks. This is greater than twice the minimal clinically important difference of 8.9 points.

The first patient was dosed in Part 2, which is the randomized, controlled portion of the BEACON trial, evaluating the safety and efficacy of LYR-220. The Company anticipates completing enrollment for the full Phase 2 BEACON trial around year-end.

"From Part 1 of the trial, we have seen that both designs of LYR-220 can be successfully placed and have now determined the one matrix design to take forward to Part 2 of the trial. In addition, we are encouraged by the preliminary efficacy improvements that we observed in SNOT-22 scores even at six weeks," said Richard Nieman, M.D., Chief Medical Officer of Lyra Therapeutics.

"We are excited to move forward to the randomized, Part 2 stage of the BEACON trial with LYR-220, adding to our continued progress with the Phase 3 ENLIGHTEN program for LYR-210 in surgically naïve CRS patients," said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. "We believe that Lyra is well positioned to potentially be the first to offer solutions for the full spectrum of CRS patients treated by ENT physicians, and we look forward to continued progress on our path to treating patients."

About Chronic Rhinosinusitis (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 65. Cardinal symptoms include nasal obstruction and congestion, facial pain and pressure, nasal discharge, and olfactory loss. The prevalence of CRS in the U.S. is estimated to be 14 million, with 8 million treated annually using medical management including topical steroid sprays and oral steroids. Roughly half of those treated fail and seek alternative medical intervention. While ENT physicians perform approximately 400,000 surgeries annually for CRS, 65% of patients have recurrent symptoms and 100% require ongoing medical management. Additionally, many patients are surgery unwilling as the current procedures are invasive, not curative, and often require long recovery times.

About LYR-220

LYR-220 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 CRS in patients with post-surgical anatomy, a population which represents roughly forty percent of the four million CRS patients who fail medical management annually. LYR-220 is designed as a non-invasive alternative to repeat sinus surgery for CRS patients who have an enlarged nasal cavity due to sinus surgery but continue to require treatment to manage CRS symptoms. LYR-220 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.

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 up to six months following a single non-invasive, in-office administration. Lyra has two product candidates 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, for surgically naïve patients, is being evaluated in the ENLIGHTEN Phase 3 clinical program, and LYR-220, for patients who have recurrent symptoms despite surgery, is being evaluated in the BEACON Phase 2 clinical trial. These two product candidates are designed to treat the estimated four million CRS patients in the U.S. that fail medical management each year. For more information, please visit 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 enrollment and success of the Phase 2 BEACON trial; the timing for topline results from the Phase 2 BEACON trial; the Company's continued progress with the Phase 3 ENLIGHTEN program for LYR-210; the safety and efficacy of LYR-220; the Company's position as a leader in the development of solutions for CRS patients treated by ENT physicians; and the anticipated success of leveraging the XTreo™ platform. 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 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; 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 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, terrorism and wars (including the developing conflict between Ukraine and Russia); 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 Securities and Exchange Commission (SEC) on August 9, 2022 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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