Lyra Therapeutics Announces First Patient Treated in Phase 2 BEACON Clinical Trial of LYR-220 in Post-Surgical Chronic Rhinosinusitis Patients

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WATERTOWN, Mass., April 25, 2022 /PRNewswire/ -- 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 that the first patient was treated in the Part 1/non-randomized portion 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 is 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 a prior surgery. Topline results from Part 1 of the Phase 2 BEACON trial are expected around year end.

"We have limited and often ineffective treatment options to alleviate persistent, burdensome symptoms in CRS patients that have been previously operated on," said Anders Cervin, MD, PhD, Professor Chair in Otolaryngology at the Centre for Clinical Research, Royal Brisbane & Women's Hospital Campus, Herston, in Queensland, Australia, and Principal Investigator in the BEACON study. "LYR-220 could represent a meaningful advance in care for these underserved patients, the majority of whom have no approved drug treatment options."

The Phase 2 BEACON trial is a controlled parallel-group study to evaluate safety, tolerability, pharmacokinetics, and efficacy comparing two designs of the LYR-220 (7500µg MF) matrix to control, over a 24-week period, in approximately 70 symptomatic adult CRS subjects who have had a prior bilateral sinus surgery. Part 1 is a non-randomized, open-label study assessing the feasibility of placement optimizing the procedure, while Part 2 will be a patient-blinded, 1:1:1 randomized assessment of two designs versus sham control. The Company anticipates completing enrollment for the full Phase 2 BEACON trial around year end.

"This represents a significant milestone for Lyra as we advance our second CRS product candidate into late-stage development, positioning us to potentially be the first to offer solutions for the full spectrum of CRS patients treated by ENT physicians," said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics. "We look forward to advancing LYR-220 through the clinic and leveraging the path of LYR-210, our investigational therapy for CRS patients with surgically-naïve anatomy, currently in a pivotal Phase 3 trial (ENLIGHTEN I), for future regulatory filings."

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 chronic rhinosinusitis (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, is being evaluated in patients who have recurrent symptoms despite surgery in the BEACON Phase 2 clinical study. 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 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 enrollment and success of the Phase 2 BEACON study, the timing for topline results from Part 1 of the Phase 2 BEACON trial and the timing for completing enrollment for the full Phase 2 BEACON trial. 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; 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 Annual Report on Form 10-K filed with the SEC on March 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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