Lyra Therapeutics Provides Corporate Update and Anticipated Milestones for 2021

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WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 22, 2021-- 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 provided a corporate update and anticipated milestones for 2021.

Corporate Update & Anticipated Milestones for 2021

- **LYR-210: Announced Positive Topline Results for the company's LANTERN Phase 2 Study of LYR-210.** In December, Lyra announced positive topline results from its LANTERN Phase 2 study of LYR-210 for the treatment of Chronic Rhinosinusitis (CRS), including:
  - 7500 mcg dose achieved statistically significant improvement in a composite score of the 4 Cardinal Symptoms of CRS at weeks 16, 20 & 24 compared to control.
  - 7500 mcg achieved statistically significant improvement in SNOT-22 at weeks 8, 16, 20 & 24 compared to control.
  - LYR-210 is the first nasal implant to achieve a benefit of up to six months after a single administration in clinical testing, and the first nasal implant to achieve a benefit in both polyp and non-polyp patients in clinical testing.
  - Lyra believes the results support a clear path to regulatory submission for LYR-210 and plans to move forward to a pivotal Phase 3 trial using the 7500 mcg dose.
- **LYR-210: End of Phase 2 Meeting with FDA Expected Mid 2021.** The company anticipates meeting with the FDA mid-2021 to discuss the results from the LANTERN Phase 2 trial, and intends to initiate a pivotal Phase 3 trial at the end of 2021.
- **LYR-210: Results From PK (pharmacokinetic) Study Expected 2Q 2021.** Lyra Therapeutics expects to announce data from its ongoing PK study, which has completed enrollment at 24 patients in the U.S., in the second quarter. The company expects to use the data from this study to support LYR-210's path to regulatory approval through a 505(b)(2) New Drug Application.
- **LYR-220: Initiation of Phase 2 Study in 2H 2021.** Lyra anticipates initiating a Phase 2 study for LYR-220 in the late second half of 2021. The company believes the LANTERN study validates its XTreo™ platform and also plans to utilize the 7500 mcg for LYR-220.
- **Cash runway into 2023.** Lyra maintains a strong balance sheet and reaffirms its previously announced guidance of having sufficient cash to fund operations into 2023. Cash and equivalents as of 31 December 2020 was $74.6 million, which exceeds prior guidance of $67-70 million.

"Having recently announced positive topline results from our LANTERN Phase 2 study of LYR-210, we enter 2021 planning and preparing for our pivotal trial, as we seek to continue development of this innovative product candidate and to ultimately bring it to millions of underserved CRS patients," said Maria Palasis, Ph.D., CEO of Lyra Therapeutics. "In addition, Lyra intends to initiate a Phase 2 trial for LYR-220 and to explore the further opportunities we believe exist for our now validated XTreo platform."

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 (ENT) diseases. The company's lead product candidate, LYR-210, is designed to deliver up to six months of continuous anti-inflammatory drug therapy to the sinonasal passages for the treatment of chronic rhinosinusitis (CRS) in patients who have not undergone surgery for the disease. Lyra is also developing LYR-220 for CRS patients who have undergone a prior surgery and have persistent disease. Beyond CRS, the company believes its XTreo™ platform, comprised of drug administered through a bioresorbable polymeric matrix, has the potential to address other disease areas by precisely, consistently and locally delivering medicines for sustained periods with a single administration.

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 lead product candidate LYR-210, the presentation of top-line results relating to the Company's Phase 2 LANTERN clinical trial for LYR-210, the Company's plans to initiate a pivotal Phase 3 study for LYR-210 at the end of 2021, the Company's anticipated announcement and use of data from its ongoing PK study, the Company's initiation of a Phase 2 study for LYR-220, and its cash guidance. 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 November 10, 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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