Lyra Therapeutics Announces FDA Clearance of Investigational New Drug Application for a Phase 2 Clinical Trial of LYR-210 for Chronic Rhinosinusitis

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LYRA THERAPEUTICS ANNOUNCES FDA CLEARANCE OF INVESTIGATIONAL NEW DRUG APPLICATION FOR A PHASE 2 CLINICAL TRIAL OF LYR-210 FOR CHRONIC RHINOSINUSITIS

Lyra to incorporate U.S. clinical sites into its ongoing global LANTERN trial, a Phase 2 clinical study of LYR-210

LYR-210 designed to provide up to six months of drug therapy in a single administration for chronic rhinosinusitis

Watertown, Mass. – January 6, 2020 – Lyra Therapeutics, Inc., 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, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for LYR-210 for the treatment of chronic rhinosinusitis (CRS), a debilitating chronic disease affecting millions of patients. LYR-210 is the company's lead product candidate that is designed to deliver continuous drug therapy to the sinonasal passages for up to six months with a single administration for the treatment of CRS. Lyra plans to incorporate U.S. clinical sites into LANTERN, its ongoing global Phase 2 clinical trial of LYR-210, which was initiated in May 2019 at sites in New Zealand, Australia and Europe.

"We believe that FDA clearance of our IND for LYR-210 is a significant milestone in our global clinical program for CRS," said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. "We look forward to continuing our progress and expanding the geography of our LANTERN study with LYR-210, as we seek to advance a new treatment paradigm for patients with this debilitating disease."

The Phase 2 LANTERN study is an ongoing randomized, sham procedure-controlled, patient-blinded clinical trial to evaluate the safety and efficacy of LYR-210 in adult patients with CRS with and without nasal polyps. In the Phase 2 LANTERN study, CRS patients who have not had sinus surgery will receive in-office bilateral administration of either one of two dose levels of LYR-210 or a sham procedure. LYR-210 is designed to be administered into the sinonasal passages through a single-use applicator and to deliver drug locally at the site of inflammation as a potential preferred alternative to surgery for patients who have failed medical management.

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 13 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.

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