Larimar Therapeutics Announces the Dosing of the First Patient in Long-term Open Label Extension Study for Nomlabofusp in Patients with Friedreich's Ataxia

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- *Study will inform on long-term safety profile and tissue frataxin levels*
- *OLE initiated with 25 mg daily subcutaneous injections of nomlabofusp*
- *Frataxin data and safety data from the OLE study are intended to help support a potential Biologics License Application ("BLA") submission for accelerated approval targeted for H2 2025*
- *Initial data expected in Q4 2024*

BALA CYNWYD, Pa., March 11, 2024 (GLOBE NEWSWIRE) -- Larimar Therapeutics, Inc. ("Larimar") (Nasdaq: LRMR), a clinical-stage biotechnology company focused on developing treatments for complex rare diseases, today announced dosing of the first patient in an open label extension (OLE) study evaluating 25 mg daily subcutaneous injections of nomlabofusp in participants with Friedreich's ataxia (FA). Nomlabofusp (CTI-1601) is a novel protein replacement therapy designed to address the root cause of Friedreich's ataxia (FA) by delivering frataxin to mitochondria.

"We are pleased to dose the first patient in our OLE study, further advancing the nomlabofusp clinical program and building on the successful completion of our Phase 2 dose escalation study. Importantly, the OLE study will inform on the long-term safety profile and tissue frataxin levels and provide a first look at real-life experience with self-administration by patients or administration by a caregiver. Participants who completed treatment in the recent Phase 2 dose exploration trial, or who previously completed a prior Phase 1 clinical trial of nomlabofusp are potentially eligible to screen for the OLE. Based on our Phase 1 and Phase 2 findings, we expect to continue daily dosing throughout the study," said Carole Ben-Maimon, MD, President, and Chief Executive Officer of Larimar. "In February we announced that we intend to pursue frataxin as a potential novel surrogate endpoint to support accelerated approval. The frataxin data, supportive pharmacodynamics and clinical outcomes information and safety data from the OLE study, along with additional nonclinical pharmacology information will be used to help support a potential BLA submission for accelerated approval targeted for the second half of 2025. We look forward to reporting initial data from the OLE study in the fourth quarter of 2024."

Larimar's Phase 2 OLE study will initially evaluate daily subcutaneous injections of 25 mg of nomlabofusp self-administered or administered by a caregiver. Key study objectives of the OLE study include safety and tolerability, pharmacokinetics, and tissue frataxin levels in peripheral tissues as well as other exploratory pharmacodynamic markers (lipid profiles and gene expression data) following long-term subcutaneous administration of nomlabofusp. Clinical measures collected during the trial will be compared to data from a synthetic control arm derived from participants in the Friedreich's Ataxia Clinical Outcome Measures Study (FACOMS) database. To escalate the dose in the OLE study, data from the 50 mg cohort of the Phase 2 dose exploration study, as well as available data from the 25 mg dose in the OLE study, will be submitted for FDA review due to the continued partial clinical hold. Initial data from the OLE study is expected in Q4 2024.

About Nomlabofusp (CTI-1601)
Nomlabofusp is a recombinant fusion protein intended to deliver human frataxin to the mitochondria of patients with Friedreich's ataxia who are unable to produce enough of this essential protein. Nomlabofusp has been granted Rare Pediatric Disease designation, Fast Track designation and Orphan Drug designation by the U.S. Food and Drug Administration (FDA), Orphan Drug Designation by the European Commission, and a PRIME designation by the European Medicines Agency.

About Larimar Therapeutics
Larimar Therapeutics, Inc. (Nasdaq: LRMR), is a clinical-stage biotechnology company focused on developing treatments for complex rare diseases. Larimar's lead compound, nomlabofusp (CTI-1601), is being developed as a potential treatment for Friedreich's ataxia. Larimar also plans to use its intracellular delivery platform to design other fusion proteins to target additional rare diseases characterized by deficiencies in intracellular bioactive compounds. For more information, please visit: https://larimartx.com.

Forward-Looking Statements
This press release contains forward-looking statements that are based on Larimar's management's beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including but not limited to statements regarding Larimar's ability to develop and commercialize nomlabofusp (also known as CTI-1601) and other planned product candidates, Larimar's planned research and development efforts, including the timing of its nomlabofusp clinical trials, interactions with the FDA and overall development plan and other matters regarding Larimar's business strategies, ability to raise capital, use of capital, results of operations and financial position, and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, among others, the success, cost and timing of Larimar's product development activities, nonclinical studies and clinical trials, including nomlabofusp clinical milestones and continued interactions with the FDA; that preliminary clinical trial results may differ from final clinical trial results, that earlier non-clinical and clinical data and testing of nomlabofusp may not be predictive of the results or success of

later clinical trials, and assessments; that the FDA may not ultimately agree with Larimar's nomlabofusp development strategy; the potential impact of public health crises on Larimar's future clinical trials, manufacturing, regulatory, nonclinical study timelines and operations, and general economic conditions; Larimar's ability and the ability of third-party manufacturers Larimar engages, to optimize and scale nomlabofusp's manufacturing process; Larimar's ability to obtain regulatory approvals for nomlabofusp and future product candidates; Larimar's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators, and to successfully commercialize any approved product candidates; Larimar's ability to raise the necessary capital to conduct its product development activities; and other risks described in the filings made by Larimar with the Securities and Exchange Commission (SEC), including but not limited to Larimar's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the SEC and available at www.sec.gov. These forward-looking statements are based on a combination of facts and factors currently known by Larimar and its projections of the future, about which it cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent Larimar's management's views only as of the date hereof. Larimar undertakes no obligation to update any forward-looking statements for any reason, except as required by law.

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