Larimar Therapeutics Publishes Nonclinical Data Supporting the Therapeutic Potential of Nomlabofusp in Patients with Friedreich's Ataxia

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- *Nonclinical findings provide evidence of the mechanism of action of nomlabofusp and support the potential use of skin FXN concentrations as a novel surrogate endpoint for Larimar's planned BLA submission in Q2 2026 seeking accelerated approval*

BALA CYNWYD, Pa., July 08, 2025 (GLOBE NEWSWIRE) -- Larimar Therapeutics, Inc. (Larimar) (Nasdaq: LRMR), a clinical-stage biotechnology company focused on developing treatments for complex rare diseases, today announced the publication of two peer-reviewed articles highlighting nonclinical data on the therapeutic potential, pharmacology, and mechanism of action of nomlabofusp as a novel frataxin (FXN) protein replacement therapy designed to address the underlying cause of Friedreich's ataxia (FA). These data were included in the briefing package reviewed by the U.S. Food and Drug Administration (FDA) in support of potentially using skin FXN concentrations as a reasonably likely surrogate endpoint (RLSE) for Larimar's registrational program seeking accelerated approval for nomlabofusp.

The articles, now available online, are titled:

- "Pharmacokinetics and Pharmacodynamics of Nomlabofusp in Non-clinical Studies of Friedreich's Ataxia" (link)
- "Nomlabofusp, a Fusion Protein of Human Frataxin and a Cell Penetrant Peptide, Delivers Mature and Functional Frataxin into Mitochondria" (link)

"We are pleased to share these two recent publications featuring nonclinical findings that provide evidence of nomlabofusp's mechanism of action, its ability to increase FXN levels in disease-relevant tissues like dorsal root ganglia, heart, and skeletal muscle after administration of doses equivalent to the dose administered in our ongoing open label study," said Carole Ben-Maimon, MD, President and Chief Executive Officer of Larimar. "Importantly, these encouraging data contributed to FDA's openness to consider the use of skin FXN concentrations as a reasonably likely surrogate endpoint in support of an accelerated approval. Our Biologics License Application (BLA) submission is planned for the second quarter of 2026. We continue to focus on executing across our near-term catalysts to further advance nomlabofusp as the first potential disease modifying therapy for patients with FA."

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, 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 and other planned product candidates, Larimar's planned research and development efforts, including the timing of its nomlabofusp clinical trials, interactions and filings with the FDA, expectations regarding potential for accelerated approval or accelerated access and time to market 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 and regulatory 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 continue 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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