

Longeveron Announces Topline Results from ELPIS II Phase 2b Clinical Trial Evaluating Laromestrocel as a Potential Treatment for Hypoplastic Left Heart Syndrome (HLHS)

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Company Announces Exploration of All Options to Maximize Shareholder Value

- The top line results showed that the ELPIS II trial did not meet its primary endpoint of improvement in right ventricular ejection fraction (RVEF) at month 12, but there were exploratory clinical endpoints that the Company is continuing to analyze and plans to discuss with the FDA to determine a potential path forward in HLHS
- Laromestrocel has maintained what Longeveron believes is a favorable safety and tolerability profile consistent with prior clinical trials, now with 644 patients treated across Longeveron's multiple clinical programs, and has shown potential efficacy in clinical studies across multiple indications and has received 5 designations from FDA
- Laromestrocel has shown positive initial results in Aging-related Frailty, including publication of clinical trial results in Cell Stem Cell and selection as a Finalist awardee in the XPRIZE Healthspan global competition
- The Company has initiated a process of optimizing cost containment and will explore all options with the goal of maximizing shareholder value

MIAMI, Sept. 16, 2026 (GLOBE NEWSWIRE) -- Longeveron Inc. (NASDAQ: LGVN), a clinical-stage biotechnology company developing cellular therapies for life-threatening, rare pediatric and chronic aging-related conditions,

today announced topline results from ELPIS II, its Phase 2b clinical trial evaluating its investigational stem cell therapy laromestrocel as an adjunct to Stage 2 palliative surgery in 40 infants with hypoplastic left heart syndrome (HLHS). The ELPIS II trial did not meet the primary efficacy endpoint of change from baseline in right ventricular ejection fraction (RVEF) at Month 12. In the intent-to-treat (ITT) population, the least-squares mean difference between treatment groups was -0.7 percentage points (95% CI: -7.3 to 5.9; p=0.8336).

Initial exploratory clinical outcomes in the as-treated analyses include:

- Over a 12-month period, there were no deaths in patients that received laromestrocel, compared to one patient in the control group, in the as-treated group
- Over a long-term follow up of transplant-free survival (up to five years across all patients), the laromestrocel arm had one event (out of 17 patients) vs. two events (out of 21 patients) in the standard-of-care arm
- Hospitalization burden was similar between arms
- Adjudicated Major Adverse Cardiovascular Events (MACE) were approximately 31% fewer in the laromestrocel arm (12 events in the treated arm vs. 19 events in the untreated arm, respectively). However, the negative binomial analysis was not statistically significant.

A sponsor-defined exploratory hierarchical composite endpoint consisting of all-cause mortality and duration of inpatient hospitalization was not statistically significant in the ITT population.

Laromestrocel demonstrated a safety profile generally consistent with prior clinical trials, and no new safety signals were identified in the study.

The Company is conducting additional analyses of the complete dataset and intends to discuss the results with the U.S. Food and Drug Administration (FDA) to determine potential next steps for the HLHS development program. FDA previously indicated its willingness to meet with the Company following completion of the study to discuss the results and potential paths forward.

Sunjay Kaushal, M.D., Ph.D., Professor of Surgery, Cardiovascular and Thoracic Surgery at University of Nevada, Las Vegas commented: "There remains a significant unmet medical need to boost the survival of the babies undergoing standard of care surgeries that still have only a 50-60% survival rate to adolescence with approximately 20% requiring heart transplant. ELPIS II provides evidence of the safety of using stem cells to address this unmet need."

Laromestrocel demonstrated a favorable safety and tolerability profile in ELPIS II, consistent with the safety experience observed across Longeveron's clinical development programs, in which 644 participants have been treated to date. Treatment-emergent adverse events (TEAEs) and treatment-emergent serious adverse events (TE-

SAEs) were reported in 94.1% and 64.7% of laromestrocel-treated participants, respectively, compared with 100% and 71.4% of control participants. No new safety signals were identified, and no TEAEs or TE-SAEs were assessed by investigators as related to laromestrocel.

The Company thanks the patients, families, investigators, and clinical sites who participated in the ELPIS II trial, as well as the NIH and the Data Coordinating and Clinical Coordinating Centers for their partnership throughout the study.

“Since its founding, Longeveron has advanced the stem cell therapy laromestrocel, completed multiple clinical trials and built a robust intellectual property portfolio,” said **Stephen H. Willard**, Chief Executive Officer of Longeveron. “The ELPIS II results continue to build our body of knowledge of laromestrocel for which we see significant promise across multiple indications, particularly in longevity and Aging-related Frailty. We will work with our advisors to evaluate all options to maximize shareholder value.”

Review of All Options to Maximize Shareholder Value

The Company announced that it has initiated a process to review all options with the goal of maximizing shareholder value. The Company intends to engage an investment bank to act as a strategic advisor for this process. In conjunction with that process, the Company will look to implement cash conservation measures to optimize cost containment.

Longevity and Aging-Related Frailty

The Company intends to pursue funding sources and other potential revenue opportunities to advance laromestrocel in longevity and Aging-related Frailty. Results from a Phase 2b clinical trial demonstrated that intravenous laromestrocel improved the physical condition of patients with age-related clinical frailty after nine months, compared to placebo. These results were published in **Cell Stem Cell** in February 2026. Further, based on these clinical trial results, Longeveron announced in August 2026 that it was selected from over 600 worldwide applicants to advance to the final phase of the **XPRIZE Healthspan** competition as a Milestone 2 Awardee team. Longeveron received the \$1,000,000 Milestone 2 Award to be used towards the future competition clinical trial in accordance with the XPRIZE competition rules, with the opportunity to compete for the XPRIZE Grand Prize of up to \$81 million.

Longeveron has been invited to participate in six upcoming longevity focused investor conferences in the fourth quarter of 2026.

About ELPIS II

ELPIS II is a Phase 2b, randomized, double-blind, multicenter, two-arm trial conducted by Longeveron in collaboration with the National Heart, Lung, and Blood Institute (NHLBI) through grants from the National Institutes

of Health (NIH) (NCT04925024). A total of 40 infants with HLHS were randomized 1:1 to receive a single intramyocardial dose of laromestrocel administered during Stage 2 palliative surgery (bidirectional Glenn or hemi-Fontan procedure) or standard of care surgery alone, and were followed for 12 months. Long-term follow-up for transplant-free survival is planned for up to 5 years.

The trial's primary endpoint was the difference between groups' change from baseline in RVEF at 12 months, assessed by cardiac magnetic resonance (CMR). As previously disclosed, FDA has advised Longeveron that RVEF alone would not be sufficient to demonstrate efficacy for regulatory approval. FDA also previously expressed willingness to meet with Longeveron when the ongoing study is completed to discuss the study results and align on a potential path forward.

Research reported in this press release was supported by the National Heart, Lung, And Blood Institute of the National Institutes of Health under Award Number UH3HL148318. The content is solely the responsibility of the Company and does not necessarily represent the official views of the National Institutes of Health.

About Hypoplastic Left Heart Syndrome (HLHS)

HLHS is a rare congenital heart defect that effects approximately 1,000 infants per year in the U.S. Infants with HLHS are born with an underdeveloped left ventricle, which creates a life-threatening condition due to the heart's inability to pump adequate amounts of blood throughout the body. The current treatment requires infants to undergo a complex three-stage heart reconstruction surgery process over the first five years of their life. Despite staged surgical palliation, long-term mortality and morbidity remain substantial, with progressive right ventricular dysfunction representing a major contributor to adverse outcomes. There is clearly an important unmet medical need to improve right ventricular function in these infants to positively impact both short- and long-term patient outcomes.

About laromestrocel (Lomecel-B®)

Laromestrocel is a living cell product made from specialized cells isolated from the bone marrow of young, healthy adult donors. These specialized cells, known as mesenchymal stem cells (MSCs), are essential to the human endogenous biological repair mechanism. MSCs have the potential to perform a number of complex functions in the body and possibly support tissue repair and regenerative signaling pathways. They also may respond to sites of injury or disease and may secrete bioactive factors that are immunomodulatory and regenerative. We believe laromestrocel MSCs may have multiple potential mechanisms of action that may lead to anti-inflammatory, pro-vascular regenerative responses, and therefore may have broad application for a range of rare and aging related diseases.

About Longeveron Inc.

Longeveron is a clinical stage biotechnology company developing regenerative medicines to address unmet medical

needs. The Company's lead investigational product is laromestrocel (Lomecel-B®), an allogeneic mesenchymal stem cell (MSC) therapy product isolated from the bone marrow of young, healthy adult donors. We believe laromestrocel has multiple potential mechanisms of action encompassing pro-vascular, pro-regenerative, anti-inflammatory, and tissue repair and healing effects with broad potential applications across a spectrum of disease areas. Longeveron is pursuing four pipeline indications: hypoplastic left heart syndrome (HLHS), Alzheimer's disease, Pediatric Dilated Cardiomyopathy (DCM) and Aging-related Frailty. Laromestrocel development programs have received five distinct and important FDA designations: for the HLHS program - Orphan Drug designation, Fast Track designation, and Rare Pediatric Disease designation; and, for the AD program - Regenerative Medicine Advanced Therapy (RMAT) designation and Fast Track designation. For more information, visit www.longeveron.com or follow Longeveron on **LinkedIn**, **X**, and **Instagram**.

Forward-Looking Statements

Certain statements in this press release that are not historical facts are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, which reflect management's current expectations, assumptions, and estimates of future operations, performance and economic conditions, and involve known and unknown risks, uncertainties, and other important factors that could cause actual results, performance, or achievements to differ materially from those anticipated, expressed, or implied by the statements made herein. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate, including discussion of ELPIS II results with the FDA and the future of the HLHS development program; our ability to pursue funding sources and potential revenue opportunities to advance laromestrocel in longevity and Aging-related frailty; our expectations regarding the review and exploration of all options and their potential impact on shareholder value; our ability to engage an investment bank or other strategic advisor; the continued listing of our Class A common stock on Nasdaq; our expectations regarding the future of the company's operations, including our clinical, development and commercialization activities; our plans to implement cash conservation measures to reduce operating expenses; and other statements regarding future events. Forward-looking statements are generally identifiable by the use of forward-looking terminology such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expects," "intend," "looks to," "may," "on condition," "plan," "potential," "predict," "preliminary," "project," "see," "should," "target," "will," "would," or the negative thereof or comparable terminology, although not all forward-looking statements contain these words, or by discussion of strategy or goals or other future events, circumstances, or effects. Additional factors that could cause actual results to differ materially from those expressed or implied in any forward-looking statements in this release include, but are not limited to, the risk that the exploration of strategic options may not result in any definitive transaction or enhance shareholder value or may create uncertainty that may adversely affect our business, financial condition, results of operations, or shareholder and investor perception; the ability of our clinical trials to demonstrate safety and efficacy of our investigational product candidates, and other positive results; our ability to successfully transition toward a more capital-efficient, asset-light operating model; our ability to secure

one or more strategic licensing partnerships for laromestrocel in our development programs; our ability to reach alignment with the FDA and other regulatory authorities on a potential path toward regulatory approval; the availability of evidence from our ongoing and future preclinical studies and clinical trials sufficient to support the Company filing a BLA for the investigational product candidate for one or more indications; the timing and focus of our ongoing and future preclinical studies and clinical trials, and the reporting of data from those studies and trials; market and other conditions, our cash position and need to raise additional capital, the difficulties we may face in obtaining access to capital, and the dilutive impact it may have on our investors; our financial performance, and ability to continue as a going concern; the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements; the size of the market opportunity for certain of our investigational product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting; our ability to scale production and commercialize the investigational product candidate for certain indications; the success of competing therapies that are or may become available; the beneficial characteristics, safety, efficacy and therapeutic effects of our investigational product candidates; our ability to obtain and maintain regulatory approval of our investigational product candidates in the U.S. and other jurisdictions; our plans relating to the further development of our investigational product candidates, including additional disease states or indications we may pursue; our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available and our ability to avoid infringing the intellectual property rights of others; the need to hire additional personnel and our ability to attract and retain such personnel; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

Further information relating to factors that may impact the Company's results and forward-looking statements are disclosed in the Company's filings with the Securities and Exchange Commission, including Longeveron's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission on March 17, 2026, its Quarterly Reports on Form 10-Q, and its Current Reports on Form 8-K. The Company operates in a highly competitive and rapidly changing environment; therefore, new factors may arise, and it is not possible for the Company's management to predict all such factors that may arise nor assess the impact of such factors or the extent to which any individual factor or combination thereof, may cause results to differ materially from those contained in any forward-looking statements. The forward-looking statements contained in this press release are made as of the date of this press release based on information available as of the date of this press release, are inherently uncertain, and the Company disclaims any intention or obligation, other than imposed by law, to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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A photo accompanying this announcement is available at

<https://www.globenewswire.com/NewsRoom/AttachmentNg/cde71c09-a5f1-424d-837b-80f8786d82a5>

Source: Longeveron

Stephen Willard

Stephen Willard, Chief Executive Officer, Longeveron Inc. (LGVN)