

NEWS RELEASE

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

2026-10-26

Important Secondary Clinical Outcome Endpoint MACE Achieved Statistical Significance

ELPIS II 2 Data in HLHS Selected for Late-Breaking Science Program Podium Presentation in the American Heart Association's (AHA) 2026 Scientific Sessions

- As previously reported, the ELPIS II trial did not meet the primary endpoint of increase in right ventricular ejection fraction (RVEF) at month 12 and the Company planned to continue analysis of additional data
- Additional analysis demonstrates an important pre-specified secondary clinical outcome endpoint, major adverse cardiac events (MACE), achieved statistical significance with 8 events in the standard of care arm versus 1 in the laromestrocel treatment arm ($P=0.043$)
- Laromestrocel was associated with fewer adjudicated clinical and safety events than the standard of care arm
- The Company believes the results suggest that laromestrocel may have the potential to meaningfully improve clinical outcomes of children with HLHS undergoing Stage II surgical palliation

MIAMI, Oct. 26, 2026 (GLOBE NEWSWIRE) -- **Longeveron Inc.** (NASDAQ: LGVN), a clinical stage biotechnology company developing cellular therapy for life-threatening, rare pediatric and chronic aging-related conditions, today announced updated results from ELPIS II following planned additional analysis conducted by the Company and the National Institutes of Health (NIH) funded trial investigators. ELPIS II is the Company's 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. Based on the secondary endpoints, laromestrocel was associated with fewer adjudicated clinical and safety events than the standard of care (SOC) arm. Additional review of the pre-specified secondary endpoint major adverse cardiac events (MACE) showed statistical significance with 8 events in the SOC arm versus 1 in the laromestrocel treatment arm ($P=0.043$). Laromestrocel demonstrated a favorable safety and tolerability profile through 12 months, with no treatment-related serious adverse events identified. The Company believes the favorable pre-specified secondary endpoint findings suggest that laromestrocel has the potential to meaningfully improve clinical outcomes of children with HLHS undergoing Stage II surgical palliation. The Company intends to request a meeting with the U.S. Food and Drug Administration (FDA) to review the results to determine potential next steps for the HLHS development program.

Results

Among the 40 randomized infants in the intention-to-treat (ITT) population, baseline and Month 12 cardiovascular magnetic resonance (CMR) were available for 28 infants (15-SOC, 13- Laromestrocel group). Mean RVEF decreased by 2.6(SD=10.5) percentage points in the SoC group and 3.3 (SD=8.4) percentage points in the Laromestrocel group, with no statistically significant difference between 2 groups (baseline adjusted difference=-1.36, 95% CI: -8.0 - 6.7, $p=0.68$).

Additional analysis for prespecified secondary clinical outcome endpoints is presented as below.

Endpoint	SOC	Laromestrocel	Comparison
Infants with ≥ 1 major cardiac event, n	9	3	-
Total major cardiac events, n	22	3	Rate Ratio=0.16 (95%CI: 0.030-0.52); $p<0.001$
Major Cardiac event rate (per 100 person-days)	0.261	0.041	-
Total MACE, n	8	1	$p=0.043$
MACE rate (per 100 person-days)	0.095	0.014	-
TR events or Valve surgery	5	0	$p=0.066$
Death, n	1	0	-
Ventricular assist device implantation, n	1	0	-

Note: Event rates were calculated over a total of 15757 person-days of follow-up. MACE - Major adverse cardiac events, TR - Tricuspid regurgitation

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.

American Heart Association's (AHA) 2026 Scientific Sessions

The Phase 2 data from the ELPIS II trial have been selected for a Late-Breaking Science Program podium presentation at the **American Heart Association's (AHA) 2026 Scientific Sessions** which will take place in Chicago on November 6-9, 2026.

Presentation

Date: Sunday, November 8, 2026

Time: 10:10am CDT

Session: Featured Science, FS.07, Heart Failure Care for Novel Phenotypes

Title: ELPIS II: A Phase 2b Randomized Clinical Trial to Evaluate the Efficacy and Safety of Laromestrocel as Adjunct Therapy During Stage II Palliation for Hypoplastic Left Heart Syndrome

About ELPIS II

ELPIS II is an investigational 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) ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04925024): NCT04925024). A total of 40 infants with HLHS were randomized 1:1 to receive a single intramyocardial dose of an investigational drug called laromestrocel that was 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.

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 affects 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 an investigational 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, anti-fibrotic, and/or pro-vascular regenerative responses, and therefore may have broad applicability 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. 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 the occurrence of a meeting or 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 strategic 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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