Humacyte Presents Long-Term Clinical Data Demonstrating Low Atherosclerosis Susceptibility in Acellular Tissue Engineered Vessel

– Analysis of ATEVs from 52 patients across five clinical trials, some implanted for more than five years, found minimal lipid buildup and no evidence of vulnerable plaques.

– First long-term clinical evaluation of atherosclerosis susceptibility in a tissue engineered vessel.

DURHAM, N.C., Nov. 16, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced new results showing that its acellular tissue engineered vessel (ATEV) were observed to have low susceptibility to atherosclerosis in patients over multiple years of implantation. The findings were presented at the 2026 ISVTE-ISACB Joint Meeting in Miami, a leading scientific meeting for vascular tissue engineering that brings together the field's major academic laboratories and companies.

"Atherosclerosis is one of the long-term threats to any vascular graft. Until now there has been no long-term clinical evidence on how bioengineered vessels hold up against it," said Juan Wang, Ph.D., Principal Scientist at Humacyte, who presented the findings. "Across more than 50 patients, many with significant cardiovascular risk factors, we saw very little evidence of the disease taking hold in the ATEV, even years after implantation. We believe that these results support the long-term durability of the ATEV as a potential option for vascular surgeons to use in the operating room."

Certain conventional vascular grafts, including a patient's own vessels, synthetic grafts, and animal-derived tissues, are known to carry a risk of atherosclerosis, which can potentially compromise their long-term performance. In the presentation, titled "Long-Term Clinical Evidence of Low Atherosclerosis Susceptibility in Acellular Tissue Engineered Blood Vessels," Humacyte scientists analyzed ATEV tissue from 52 patients who received the ATEV for arteriovenous (AV) access in hemodialysis or for peripheral artery bypass across five clinical trials. Implant durations ranged from less than one week to more than five years.

"Durability is one of the most important questions surgeons ask about any vascular conduit," added Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "This data, drawn from patients implanted for as long as five years, suggest that the ATEV's biology works over time. That matters as we work to bring the ATEV to more patients including, if approved by the FDA, those who need long-term reliable access for hemodialysis."

Despite a high prevalence of atherosclerosis risk factors in the patient population, the research showed:

- Minimal lipid deposition (an average of only 0.6% of tissue area) and scarce foam cell formation, both of which are indicators of early atherosclerotic plaque development.
- Inflammatory cells, including macrophages, were largely absent from the ATEV wall.
- Over 95% of ATEV explants evaluated showed no or only a minor presence of early markers for atherosclerosis, even after more than five years of implantation.
- Only 4.7% of ATEVs studied showed some atypical fatty streaks and none showed evidence of vulnerable plaques.
- Consistent with previous findings, the ATEVs were progressively repopulated with the patient's own smooth muscle and endothelial cells and adaptively remodeled.

The researchers attribute the ATEV's low susceptibility to atherosclerosis to its acellular, biocompatible composition, and low innate proteoglycan content which may support non-inflammatory repopulation by the patient's own cells and limit the retention of the lipids and lipoproteins that drive plaque formation.

For uses other than the FDA approval in the extremity vascular trauma indication, the ATEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

About Humacyte

Humacyte, Inc. (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues, advanced tissue constructs, and organ systems designed to improve the lives of patients and transform the practice of medicine. The Company develops and manufactures acellular tissues to treat a wide range of diseases, injuries, and chronic conditions. Humacyte's Biologics License Application for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication was approved by the FDA in December 2024. ATEVs are also currently in late-stage clinical trials targeting other vascular applications, including arteriovenous (AV) access for hemodialysis and peripheral artery disease (PAD). Preclinical development is also underway in coronary artery bypass grafts, pediatric heart surgery, treatment of type 1 diabetes, and multiple novel cell and tissue applications. Humacyte's 6mm ATEV for AV access in hemodialysis was the first product candidate to receive the FDA's Regenerative Medicine Advanced Therapy (RMAT) designation and has also received FDA Fast Track designation. Humacyte's 6mm ATEV for urgent arterial repair following extremity vascular trauma and for advanced PAD also have received RMAT designations. The ATEV received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense. For more information, visit www.Humacyte.com.

Forward-Looking Statements

This press release contains forward-looking statements that are based on beliefs and assumptions and on information currently available. In some cases, you can identify forward-looking statements by the following 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, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this press release include, but are not limited to, our plans and ability to commercialize Symvess and, if approved by regulatory authorities, our product candidates, successfully and on our anticipated timelines; the degree of market acceptance of and the availability of third-party coverage and reimbursement for Symvess and, if approved by regulatory authorities, our product candidates; our ability to manufacture Symvess and, if approved by regulatory authorities, our product candidates in sufficient quantities to satisfy our clinical trial and commercial needs; the anticipated benefits of our ATEVs relative to existing alternatives; our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines; our plans, anticipated timeline and ability to file applications for, and obtain marketing approvals from, the FDA and other regulatory authorities, including the European Medicines Agency, for our ATEVs and product candidates; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding the results of our clinical trials, and regarding our ongoing or planned clinical trials; the anticipated characteristics and performance of our ATEVs and the public perception thereof; the implementation of our business model and strategic plans for our business; and the timing or likelihood of regulatory filings, acceptances and approvals. We cannot assure you that the forward-looking statements in this press release will prove to be accurate. These forward-looking statements are subject to a number of significant risks and uncertainties that could cause actual results to differ materially from expected results, including, among others, changes in applicable laws or regulations, the possibility that Humacyte may be adversely affected by other economic, business, competitive and/or reputational factors, and other risks and uncertainties, including those described under the header “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2025 and Form 10-Q for the quarter ended September 30, 2026, each filed by Humacyte with the SEC, and in future SEC filings. Most of these factors are outside of Humacyte’s control and are difficult to predict. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Except as required by law, we have no current intention of updating any of the forward-looking statements in this press release. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

Humacyte Investor Contact:
Joyce Allaire
LifeSci Advisors LLC
+1-617-435-6602
jallaire@lifesciadvisors.com
investors@humacyte.com

Humacyte Media Contact:
Rich Luchette
Precision Strategies
+1-202-845-3924
rich@precisionstrategies.com
media@humacyte.com