



Humacyte Announces Lancet Digital Health Publication of V007 Phase 3 Hemodialysis Access Trial Results

- Phase 3 results highlight benefits of ATEV for patients at higher risk of fistula failure, including all women and men with obesity and diabetes –
- Publication provides peer-reviewed validation for V007 Phase 3 data, and complements recent release of Phase 3 V012 data showing ATEV outperformed standard of care for women on dialysis –

DURHAM, N.C., Aug. 19, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced the publication of one-year results from the V007 Phase 3 clinical trial of the acellular tissue engineered vessel (ATEV) in arteriovenous (AV) access for hemodialysis patients in *The Lancet Digital Health*, a leading peer-reviewed journal in the *Lancet* family.

The publication, titled "A Multi-center Randomized Trial of a Bioengineered Acellular Tissue Engineered Vessel versus Autogenous Fistula for Hemodialysis Access," demonstrates the positive findings from Humacyte's V007 trial, previously presented at major medical conferences, showing the superiority of the ATEV over autogenous arteriovenous fistula (AVF) for hemodialysis vascular access after one year of follow up, particularly for all female patients and male patients with obesity and diabetes, groups that often face higher rates of AVF failure.

"Reliable hemodialysis access is critical for patients with end-stage kidney disease, yet remains a challenge for many, especially those with higher risk profiles," said Mohamad A. Hussain, M.D., Ph.D., lead author of the publication and Vascular and Endovascular Surgeon at Heart and Vascular Institute, Mass General Brigham and Associate Professor of Surgery at Harvard Medical School. "This publication in *The Lancet Digital Health* provides additional validation of these results and highlights the potential of ATEV as an alternative for patients who may be less likely to benefit from AV fistulas."

"Publication in *The Lancet Digital Health* is a significant milestone for Humacyte and an important validation of our Phase 3 dialysis data. These results demonstrate that the ATEV can offer a better option for the patients who need it most, particularly all women and men with obesity and diabetes, who too often face poor outcomes with traditional fistulas," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "With the V007 and V012 results we believe we have built a compelling case to bring this technology to the patients who stand to benefit most."

Positive two-year results from the V007 Phase 3 trial, announced in November 2025 at the American Society of Nephrology's *Kidney Week 2025*, further demonstrated the durability of ATEV's benefits over time. Additionally, Humacyte reported top-line interim results from its V012 Phase 3 study June 11, 2026 at the Society of Vascular Surgery's (SVS) Vascular Annual Meeting (VAM) in Boston. V012 is specifically focused on female patients with end-stage renal disease (ESRD) needing hemodialysis — a population in which the V007 one-year data already showed meaningful advantages for ATEV over traditional fistulas. As a result of meeting the primary superiority endpoint in V012, Humacyte plans to submit a supplemental Biologics License Application (sBLA) to expand the Symvess® label to include a second indication in AV access for hemodialysis in the second half of 2026.

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 ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding our ongoing or planned clinical trials; the anticipated characteristics and performance of our ATEVs; the implementation of our business model and strategic plans for our business; our ability to

execute and achieve the expected benefits of our cost-saving measures and whether our efforts will result in further actions or additional asset impairment charges that adversely affect 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 June 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.

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