



Humacyte Announces Phase 3 V012 Trial Results for ATEV in Women Requiring Hemodialysis Access Accepted for a Late-Breaking Session Presentation at ASN Kidney Week 2026

- Interim Phase 3 findings will be presented in a prestigious late-breaking oral session at the leading meeting for kidney health professionals.

- Randomized trial compares the acellular tissue engineered vessel (ATEV) with autogenous arteriovenous fistula in female patients with end-stage kidney disease.

- Supplemental BLA in AV access for hemodialysis expected to be submitted to FDA this quarter.

DURHAM, N.C., Oct. 12, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced that interim results from its V012 Phase 3 clinical trial have been accepted for a late-breaking oral presentation at the American Society of Nephrology (ASN) Kidney Week 2026, taking place October 21–25 in Denver, Colorado.

ASN Kidney Week is the world's largest nephrology meeting, bringing together more than 12,000 kidney professionals each year. The late-breaking presentation provides the opportunity to share the V012 data directly with the clinicians who manage dialysis access every day.

V012 is a Phase 3 randomized controlled trial comparing Humacyte's acellular tissue engineered vessel (ATEV) with autogenous arteriovenous fistula (AVF) for hemodialysis access in female patients with end-stage kidney disease (ESKD). The Phase 3 results will be presented by Prabir Roy-Chaudhury, M.D., Ph.D., of the University of North Carolina at Chapel Hill School of Medicine.

Presentation details:

- **Title:** Randomized Controlled Trial of an Acellular Tissue Engineered Vessel vs. Arteriovenous Fistula for Hemodialysis Access in Female Patients with ESKD: A Phase 3 CLN-PRO-V012 Interim Analysis
- **Presenter:** Prabir Roy-Chaudhury, M.D., Ph.D., University of North Carolina at Chapel Hill School of Medicine
- **Authors:** Mohamad A. Hussain (Mass General Brigham); Prabir Roy-Chaudhury (University of North Carolina at Chapel Hill School of Medicine); Sophia Bou-Ghannam, Laura E. Niklason and Shamik J. Parikh (Humacyte)
- **Session:** Late-Breaking Research Orals: Dialysis and Transplantation
- **Date and time:** Thursday, October 22, 2026, 4:40–4:50 PM MT
- **Location:** Four Seasons Ballroom 2, Colorado Convention Center, Denver
- **Abstract number:** TH-OR113

"Women on dialysis are more likely than men to experience fistula failure and to remain dependent on catheters," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "V012 was built to test whether the ATEV can offer a better option for these patients, and we look forward to Dr. Roy-Chaudhury sharing the Phase 3 results with the nephrology community at ASN Kidney Week."

The results from V012, supported by the results from two previously completed Phase 3 trials in hemodialysis access, form the clinical foundation for Humacyte's planned supplemental Biologics License Application to expand the Symvess® label to include AV access for hemodialysis, which the Company has targeted for submission to the FDA this quarter.

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, including our V012 Phase 3 clinical trial, 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 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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