



Humacyte at ASN Kidney Week: Phase 3 Trial Built for Women Shows ATEV Advantage Over Fistula, Getting Patients Off Catheters Months Sooner

- The presenter, Dr. Roy-Chaudhury said, "These results give the nephrology community a strong reason to rethink our approach to access decisions for women and, once approved by the FDA, to consider the ATEV as a meaningful new option."
- In a planned interim analysis, women implanted with the ATEV averaged 220 catheter-free days in the first year compared to 129 days with arteriovenous fistula, meeting the trial's primary endpoint of superiority.
- ATEV recipients achieved functional access significantly faster than AV fistula recipients, with a median of 1.7 months compared to 5.3 months with an AV fistula.

DURHAM, N.C., Oct. 23, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced that positive interim results from the V012 Phase 3 clinical trial of the acellular tissue engineered vessel (ATEV) in arteriovenous (AV) access for female hemodialysis patients were presented at the American Society of Nephrology's (ASN) *Kidney Week 2026*, one of the world's premier nephrology meeting, held this year in Denver, Colorado. V012 is the first randomized clinical trial specifically designed to evaluate the ATEV against AV fistula for hemodialysis access in women with end-stage kidney disease (ESKD).

In the V012 Phase 3 trial, women implanted with the ATEV achieved functional access more than three months sooner and spent significantly more time free of dialysis catheters over the first year than women who received an AV fistula, which is the current standard of care for hemodialysis access across all patients. Women have historically had poorer outcomes with AV fistula procedures, including higher rates of maturation failure, longer times to functional access, and greater reliance on infection-prone catheters.

The late-breaking podium presentation, delivered in the Late-Breaking Research Orals: Dialysis and Transplantation session, titled "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," was presented on Thursday, October 22, 2026 by Prabir Roy-Chaudhury, M.D., Ph.D., FASN, 2025 President of the American Society of Nephrology and Co-Director of the University of North Carolina Kidney Center.

"Every woman in this study was judged by her surgeon to be a candidate for a fistula, but more than a third of those fistulas failed to mature within a year in this study," said Dr. Roy-Chaudhury. "That tells us that even in the right patients, we cannot count on a fistula to work, or to work in time. In V012, women with the ATEV reached usable access months sooner and spent significantly less time on a catheter. **These results give the nephrology community a strong reason to rethink our approach to access decisions for women and, once approved by the FDA, to consider the ATEV as a meaningful new option for the patients who need it most.**"

The V012 Phase 3 trial (NCT05908084) is a comparative study designed to enroll approximately 150 female hemodialysis patients, randomized 1:1 to receive either the ATEV or an AV fistula for hemodialysis access. All women enrolled were receiving hemodialysis through a catheter and were considered suitable candidates for AV fistula creation in the judgment of their treating surgeons. The primary efficacy endpoint is catheter-free days from access creation through 365 days, or until access abandonment, whichever occurs first. Results reflect a prespecified interim analysis of the first 80 patients. Because the trial met its primary endpoint, enrollment was stopped.

In the interim analysis, women implanted with the ATEV averaged 91 more catheter-free days over the first 12 months than women receiving an AV fistula (220.4 days compared to 129.3 days; $p < 0.001$). Despite all patients being judged at the outset as suitable for fistula creation, only approximately 65% of AV fistulas achieved functional maturation by Month 12, with maturation largely plateauing by Month 9, leaving approximately one-third of women in the fistula arm without a functionally mature fistula at one year.

"Prolonged catheter dependence is one of the most serious problems a surgeon encounters in dialysis care. A bioengineered vessel that women can use sooner, and that keeps them off a catheter longer, could make a real difference," added Mohamad A. Hussain, M.D., Ph.D., a vascular and endovascular surgeon-scientist at the Heart and Vascular Institute, Mass General Brigham, and Associate Professor of Surgery at Harvard Medical School.

"For a woman receiving maintenance hemodialysis, it's important to have vascular access options that can be individualized to meet their needs. Less is more when it comes to getting women to usable access sooner - less catheter time is more time to enjoy non dialysis activities without having to worry about the risks of catheter-related infection, hospital visits, and uncertainty," said Charmaine Lok, M.D., Professor of Medicine at the Faculty of Medicine, University of Toronto and Senior Scientist at the Toronto General Hospital Research Institute.

The safety profile of the ATEV was comparable to that of AV fistula. Fewer dialysis access infections were observed with the ATEV, approximately 6 per 100 patient-years, compared to 23 per 100 patient-years with AV fistula. None of the infections in the ATEV group were related to the vessel itself, and no spontaneous ruptures were reported in either group.

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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