Humacyte Announces Presentation at VASA Meeting of Research Highlighting Self-Repair of ATEV After Cannulation for Dialysis Access

- Dialysis access requires frequent cannulation, often exceeding 300 needle punctures annually -

- The ATEV was observed to maintain long-term structural integrity and self-repair with smooth muscle cell repopulation despite repeated cannulations -

- Humacyte anticipates that top-line interim results from its ongoing V012 Phase 3 study in dialysis access will be available for reporting in June -

DURHAM, N.C., May 26, 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 presentation of research providing evidence of self-repair of the acellular tissue engineered vessel (ATEV) after cannulation for dialysis access at the Vascular Access Society of the Americas (VASA) *2026 Vascular Access for Dialysis Symposium* in Salt Lake City, Utah. The presentation, titled “Self-repair of Acellular Tissue Engineered Vessels (ATEV) after Cannulation for Dialysis Access,” was delivered by Maisha Clancy, MA, Process Development Engineer at Humacyte. Research demonstrated that despite repeated cannulations for dialysis access, the ATEV was observed to maintain long-term structural integrity self-repair with smooth muscle cell repopulation in explants up to 5.5 years post-implantation.

Arteriovenous (AV) fistulas remain the standard of care for vascular access in patients undergoing dialysis, with arteriovenous grafts, including ePTFE grafts, also used as alternatives. Both types require frequent cannulation to provide access to the patient’s blood for dialysis, often exceeding 300 needle punctures annually. Repetitive cannulation can damage the conduit wall and endothelium, contributing to hematoma, pseudoaneurysm, infection, thrombosis, and stenosis. Under the research program presented at the VASA meeting, histological characterization of cannulation tracts was performed in explanted ATEV and ePTFE samples that had been used as AV access conduits for up to 5.5 years.

Researchers observed that despite repeated cannulations, ATEVs maintained long-term structural integrity in explants up to 5.5 years post-implantation. Repeated cannulation sites in the ATEVs showed evidence of self-repair, with smooth muscle cell repopulation of the graft wall and access tracts. Functional tissue remodeling occurred at the ATEV cannulation sites, including capillary ingrowth and organized collagen deposition with predominant collagen III expression. Growth factor, glycoprotein, and proteoglycan presence was observed, evidencing matrix regeneration in the ATEVs. In cannulation sites and cannulation adjacent walls, ATEVs were observed to have greater resistance to bacterial infection than ePTFE grafts.

"These findings support the continued evaluation of ATEVs as a potential durable, self-repairing, and infection-resistant vascular access solution for long-term hemodialysis in patients at high risk for AV fistula failure," said Clancy. "The observations of lower grade injury in ATEVs, together with evidence of active cellular repair and bacterial containment, highlights their regenerative capacity and ability to support improved host defenses."

Humacyte anticipates that top-line interim results from its ongoing V012 Phase 3 study in dialysis access will be available for reporting on June 11, 2026 at the Society of Vascular Surgery’s (SVS) Vascular Annual Meeting (VAM) in Boston. The V012 study is specifically focused on female patients with end-stage renal disease (ESRD) requiring dialysis, a population in which results from the completed V007 Phase 3 trial already showed meaningful advantages for ATEV over AV fistulas. Subject to results from the V012 study, Humacyte plans to submit a supplemental Biologics License Application (sBLA) for a second indication in AV access for hemodialysis during 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 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 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 March 31, 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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