Humacyte Announces Presentations at VEITHsymposium Highlighting Positive Acellular Tissue Engineered Vessel (ATEV™) Clinical Results

– Post-implantation analysis of ATEVs demonstrates progressive recellularization with host cells, transforming the ATEV into a multi-layered living tissue similar to that of native blood vessels –

– Positive outcomes for dialysis patients suffering from Steal syndrome who were treated with the ATEV –

– Additional presentations report durable two-year outcomes for patients treated in Ukraine conflict, superior two-year outcomes for female dialysis patients, and results for patients treated with torso arterial trauma –

DURHAM, N.C., Nov. 20, 2025 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced highlights of five podium presentations on the Company's acellular tissue engineered vessel (ATEV™) made yesterday at the 52nd Annual Symposium on Vascular and Endovascular Issues, Techniques And Horizons (VEITHsymposium), in New York, NY. The VEITHsymposium is a premier educational event for vascular surgeons, interventional radiologists, interventional cardiologists, and other vascular specialists.

The ATEV's ability to remodel into living vascular tissue was highlighted in a podium presentation titled "In Vivo Regeneration of Bioengineered Blood Vessels: Histologic Evaluation of Acellular Tissue Engineered Vessels After Long-Term Clinical Use," by Luigi Pascarella, MD, Division Chief of Vascular Surgery, Associate Chair of Education, UNC Medical School. The presentation described a study in which tissue samples from ATEVs implanted in patients, taken up to 200 weeks post implantation, were analyzed using immunochemistry. The ATEVs are decellularized at the end of the production process to eliminate immunogenicity and allow them to be universally implanted into any patient without fear of rejection. Post-implantation analysis of the ATEVs revealed progressive recellularization with host cells including smooth muscle cells and endothelial cells, transforming the ATEV into a multi-layered living tissue similar to that of native blood vessels.

"Observing these acellular tissue-engineered vessels transform into living, self-repairing vascular tissue over time is nothing short of remarkable," said Dr. Pascarella. "The evidence of host cell integration and adaptive remodeling gives us real hope for a future where vascular grafts are not just replacements, but regenerative solutions. The ATEV's ability to remodel into living vascular tissue capable of self-repair, combined with its absence of immunogenicity, supports its potential as a durable and biocompatible conduit for treating vascular disease and injury."

Outcomes of dialysis patients suffering from Steal syndrome who were treated with the ATEV were detailed in a podium presentation titled "Use of the Acellular Tissue Engineered Vessel (ATEV) in Distal Revascularization and Interval Ligation (DRIL) Procedures for Dialysis Access-Associated Steal Syndrome: Case Series from the CLN-PRO-V005," by Ernest E. Moore, MD, Director of Research at the Ernest E. Moore Shock Trauma Center at Denver Health in Denver, Colorado. Steal syndrome following arteriovenous fistula creation for dialysis can cause disabling ischemia, most commonly requiring surgical intervention. Distal Revascularization and Interval Ligation (DRIL) is a standard technique, typically using autologous vein. Dr, Moore reported on the outcome of four cases from the V005 Phase2/3 vascular trauma study in which ATEV was used as the conduit for DRIL procedures to reconstruct the brachial artery in patients with dialysis access–associated steal syndrome. Patients were followed for up to 35.9,months, and the ATEV was observed to have durable patency, safety and freedom from graft-related infection or rupture.

"The durability and safety profile of the ATEV in DRIL procedures is compelling, said Dr, Moore. "Maintaining long-term patency without graft-related infection—even in patients with severe comorbidities—underscores its potential as a biologic alternative when autologous vein is not feasible. The ATEV's performance in these complex DRIL cases suggests we can move beyond the constraints of vein availability toward a regenerative solution.""

Additional presentations related to the ATEV made yesterday at the VEITHsymposium included:

- "Human Acellular Vessels* vs. Autologous Vein Grafts for Combat Vascular Trauma: Two-Year Outcomes from the War in Ukraine," presented by Oleksander V. Sokolov, MD, PhD, a Ukrainian vascular surgeon who treated wartime patients with Symvess under a humanitarian program. Dr. Sokolov reported that trauma patients with wartime injuries treated with the ATEV were observed to have a continued high rate of patency, 100% limb salvage, and zero cases of conduit infection in 17 patients with extremity injuries followed for up to two years.

- "Two-Year Outcomes in Female Patients from A Prospective Randomized Trial of Humacyte's Acellular Tissue Engineered Vessel vs. Autologous Arteriovenous Fistula for Hemodialysis," presented by Mohamad A. Hussain, MD, PhD, RPVI, FAHA, FRCSC, FACS, Vascular and Endovascular Surgeon-Scientist at Brigham and Women's Hospital, Core Faculty at the Center for Surgery and Public Health, and Assistant Professor of Surgery at Harvard Medical School. Dr. Hussain reported that the ATEV was observed to have superior patency at 24 months, and superior duration of use over two years, compared to autogenous fistula in females, a high-need subgroup with historically poor outcomes with AV fistula procedures.

- "Use of the Acellular Tissue Engineered Vessel for Torso Arterial Trauma: Case Reports from the CLN-PRO-V005 Trial," presented by Gregory A. Magee, MD, MSc, Frank J. Veith, MD Clinical Professor of Vascular and Endovascular Surgery, Department of Surgery at NYU Grossman School of Medicine. Dr, Magee reported on the outcomes of high-acuity torso injury cases implanted with the ATEV showing feasibility of ATEV use in torso arterial trauma.

Two additional presentations related to the ATEV will be made today at the VEITHsymposium:

- “Clinical Effectiveness of an Acellular Tissue Engineered Vessel: Review of Published Outcomes Across Multiple Vascular Indications,” to be presented by Michael Curi, MD.

- “Update On The Tissue Engineered Human Biological Arterial Grafts (Humacyte): 3-Year Clinical Results in Civilian And Military Settings: Indications, Advantages And Unanswered Questions,: to be presented by Todd E. Rasmussen, MD, FACS and Charles J. Fox, MD, FACS.

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, 2024 and Form 10-Q for the quarter ended September 30, 2025, 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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