Humacyte Announces Presentation of Positive Two-Year Results from Phase 3 Dialysis Access Trial at the American Society of Nephrology's Kidney Week 2025

– The ATEV™ was observed to have superior duration of use over 24 months compared to autogenous fistula in high-need subgroups with historically poor outcomes with AV fistula procedures –

– The significantly longer duration of ATEV use in these high-need patients could greatly reduce reliance on catheters for dialysis access, a major cause of complications, morbidity and cost in dialysis patients –

DURHAM, N.C., Nov. 10, 2025 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced the presentation of positive two-year results from the V007 Phase 3 clinical trial of the acellular tissue engineered vessel (ATEV) in arteriovenous (AV) access for hemodialysis patients at the American Society of Nephrology's (ASN) *Kidney Week 2025*, the premier nephrology meeting, in Houston.

In the V007 Phase 3 trial, the ATEV was observed to have superior duration of use over 24 months as compared to autogenous fistula in female, obese and diabetic patients. Autogenous fistula is the current gold standard for hemodialysis access across all patients. However, female, obese and diabetic patients comprise high-need subgroups, having historically poor outcomes with AV fistula procedures. The podium presentation, titled "Two-Year Outcomes from a Prospective Randomized Trial of Humacyte's Acellular Tissue Engineered Vessel Versus Autologous Arteriovenous Fistula for Hemodialysis Access," was presented on Saturday, November 8, 2025 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.

"In the V007 study the ATEV provided a clinically meaningful advantage in early usability and functional patency, enabling faster, more reliable dialysis initiation, especially in female, obese, and diabetic patients," said Dr. Hussain. "As a biologic conduit, the ATEV could be game changing by improving arteriovenous access in many hemodialysis patients. Of particular importance were the positive results in female, obese, and diabetic patients, groups which typically have poor outcomes with autogenous fistula procedures and historically have limited treatment alternatives for hemodialysis access. The significantly higher duration of access over two years in these underserved patients could greatly reduce reliance on catheters for arteriovenous access, a major cause of complications and treatment costs in patient care."

The V007 Phase 3 trial (NCT03183245) was a prospective, multi-center, randomized clinical study in 242 hemodialysis patients in the United States. Enrolled individuals were randomly assigned to receive either the ATEV or an AV fistula for hemodialysis access and were followed for up to 24 months. Under the statistical analysis plan for the trial, the primary efficacy assessment compared functional patency (usability for hemodialysis access) at six months and secondary patency (blood flow through the conduit) at 12 months, as co-primary endpoints. As previously reported, the ATEV was observed to have superior patency and usability for dialysis at six and 12 months (co-primary endpoints), respectively, compared to autogenous fistula in all patients as well in the high-risk subgroups.

The V007 study also had a secondary endpoint of duration access use over 24 months, which continued to show superiority of the ATEV over AV fistula in female, obese and diabetic patients. In female patients (n=70) over 24 months, patients implanted with the ATEV had 15.8 months of average duration of usage, compared to 10.0 months for patients receiving an AV fistula ($p<0.0137$). In the target population of females, and males with obesity and diabetes (n=110), patients implanted with the ATEV had 14.8 months of average duration of access use compared to 9.1 months patients receiving an AV fistula ($p=0.0114$). For all patients in the study (n=242), patients receiving an ATEV had 13.3 months of average duration of access use compared to 12.3 months for AV fistula ($p=0.7446$). The results are consistent with Humacyte's stated strategy of targeting patients at higher risk of AV fistula failure: Females, and males with obesity and diabetes, which comprise over half of the hemodialysis population.

"The two-year data from the V007 trial is truly groundbreaking," said Dr. Roy Fujitani, Professor of Vascular and Endovascular Surgery at UC Irvine. "Seeing the ATEV outperform AV fistulae in high-risk patients—particularly women, diabetics, and those with obesity—is incredibly encouraging. This represents a pivotal shift in dialysis access strategy, introducing a durable, low-infection alternative that may dramatically improve outcomes for patients at elevated risk of fistula failure."

Researchers concluded that after 24 months of follow up, there were no unexpected side effects observed in patients implanted with the ATEV. In the study, patients implanted with the ATEV had a comparable safety profile to patients receiving an AV fistula with low rates of infection and a lower need for maturation or surgical revision procedures compared to AV fistula. Patients implanted with the ATEV experienced more thrombosis and narrowing/stenosis events requiring interventions than patients receiving an AV fistula, however the majority of these cases were successfully treated.

"These results are incredibly promising and the ATEV's performance in high-risk patients signals a major advancement in dialysis access," said Jason Burgess MD, Surgical Specialists of Charlotte, PA. "As a clinician who participated in this study, I'm excited by the potential of a bioengineered vessel that not only improves usability but also reduces catheter dependence. I look forward to integrating ATEV into future treatment strategies for patients who historically have had poor outcomes with AV Fistula procedures."

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.

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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 March 31, 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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Source: Humacyte, Inc