Humacyte ATEV Met Superiority Primary Endpoint Compared to Standard of Care AV Fistula in Interim Analysis of V012 Phase 3 Study in Female Dialysis Access Patients

- Humacyte plans to file a supplemental Biologic License Application (BLA) with the Food and Drug Administration (FDA) during the second half of 2026 -

- The ATEV met V012's primary endpoint and was observed to have superior catheter-free days (p=0.00070) compared to autologous arteriovenous (AV) fistula, the current standard of care -

- The ATEV's ability to reduce time on catheter has the potential to improve patient outcomes and lower the burden of dialysis costs on the healthcare system. -

DURHAM, N.C., June 10, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced positive top-line interim results for the V012 Phase 3 study of the acellular tissue engineered vessel (ATEV) in female patients for dialysis access. In a prespecified interim analysis conducted in the first 80 patients enrolled in the study, the V012 trial's primary endpoint was met with the ATEV observed to have an average of 91 more catheter-free days compared to autologous arteriovenous (AV) fistula, the current standard of care.

In accordance with the study protocol, as a result of meeting the primary endpoint, study enrollment will terminate and existing patients will continue to be followed as per protocol. Humacyte plans to file a supplemental BLA with the FDA during the second half of 2026. The currently planned target indication is focused on adult patients with end-stage kidney disease who are at increased risk of AV fistula maturation failure.

"We are excited to announce positive clinical results for the Phase 3 V012 study, particularly as these results represent a real advancement in the dialysis care for female patients, a population that currently has suboptimal access options," said Shamik Parikh, MD, Humacyte's Chief Medical Officer. "Patients receiving an ATEV had an average of three months additional catheter-free time as compared to AV fistula, a highly significant outcome. Reducing patients' reliance on catheters is critical given the high risk of infection and complications seen with indwelling catheters. These results reinforce the potential of our bioengineered human blood vessel to improve outcomes while addressing longstanding challenges in dialysis access."

The V012 clinical study is designed to demonstrate the efficacy and safety of the ATEV as a dialysis access method compared to autologous AV fistula in female dialysis patients, a high-unmet-need population. V012 is a Phase 3, prospective, multi-center, open label, randomized, two-arm comparative study conducted in the United States in up to 150 patients, with 120 patients are currently enrolled. The primary measure of efficacy is total days free from in-dwelling catheter ("catheter-free days") until 365 days after access placement, or until access abandonment, whichever occurs first. A prespecified interim analysis was conducted after the first 80 patients enrolled had completed 12 months of follow-up. In this analysis, patients implanted with the ATEV achieved an average of 220 catheter-free days compared to 129 catheter-free days for patients who received an AV fistula. The result was statistically significant (p=0.00070), meeting the primary endpoint of the study.

The primary safety measure in the V012 study is the number and severity of infections related to all accesses (including catheters) from the date of access creation until 365 days thereafter. Patients receiving the ATEV incurred infections at a rate of six per 100 patient years, as compared to 23 per 100 patient years for patients receiving an AV fistula procedure. There were no study access-associated infections reported in the ATEV patients, while there were three among the AV fistula patients. There were no spontaneous ruptures reported in either of the treatment groups. The overall benefit risk profile of the ATEV was observed to be favorable, with no new or unexpected safety signals identified.

Over 800,000 Americans are currently living with end stage kidney disease, and nearly 500,000 Americans depend on hemodialysis for survival. Dialysis treatments require establishing a durable point of access to a patient's circulatory system in order to transfer large volumes of blood to the dialysis machine, and then back into the patient. However, the current standard of care for establishing access for hemodialysis has significant risks and shortcomings. Catheters, which are tunneled underneath the skin, have high rates of bloodstream infections and other complications. Autogenous AV fistulas often fail to function after surgery, particularly for women, forcing patients to rely on infection-prone catheters. In addition, many patients are not suitable candidates for AV fistula placement due to gender, small vessel anatomy, advanced age, obesity, or other comorbidities.

Humacyte's ATEV is a bioengineered human tissue derived from cultured human cells that is designed to be a universally implantable vascular conduit for use in vascular replacement and repair. The ATEV has been observed to have a low rate of infection in multiple clinical trials. The ATEV is designed to be available off-the-shelf, and ready whenever surgeons need it, potentially saving valuable operating room time and improving patient outcomes.

Results from the V012 Phase 3 study will be presented the evening of June 11, 2026 at the Society for Vascular Surgery's (SVS's) Vascular Annual Meeting (VAM) in Boston in the Women's Health seminar.

For uses other than the FDA approval in the extremity vascular injury 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 injury 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 injury 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 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; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates; 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.

Humacyte Investor Contact:
Joyce Allaire
LifeSci Advisors LLC
+1-617-435-6602
jallaire@lifesciadvisors.com
investors@humacyte.com

Humacyte Media Contact:
Rich Luchette
Precision Strategies
+1-202-845-3924
rich@precisionstrategies.com
media@humacyte.com