Humacyte's Bioengineered Blood Vessel Outperforms the Standard of Care for Women on Dialysis in Phase 3 Results Presented at the Society for Vascular Surgery Vascular Annual Meeting

– Positive results from the V012 Phase 3 study were presented at the Society for Vascular Surgery's Vascular Annual Meeting in Boston –

– Women who received Humacyte's ATEV experienced an average of three more months without a dialysis catheter than women who received AV fistula, the current standard of care –

– Company to hold investor event today, June 15th, at 5:00 p.m. ET –

DURHAM, N.C., June 15, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology company that develops bioengineered human tissues, presented detailed results from its V012 Phase 3 study showing that the Company's bioengineered blood vessel – the acellular tissue engineered vessel, or ATEV – outperformed autologous arteriovenous (AV) fistula, the current standard of care, for women on dialysis. The results were presented at a Women's Health seminar during the Society for Vascular Surgery's (SVS's) Vascular Annual Meeting (VAM) in Boston.

"For too long, women on dialysis have had to settle for access options that often don't work well for them," said Laura Niklason, MD, PhD, Chief Executive Officer of Humacyte. "This study shows that our bioengineered blood vessel can keep patients off catheters longer than the current standard of care, with fewer infections. That is a meaningful difference for patients, and we look forward to using this data to file a supplemental BLA with the FDA later this year."

"Every day a patient spends on a catheter is a day at higher risk of infection," added Shamik Parikh, MD, Chief Medical Officer of Humacyte. "Giving women an average of three more months without a catheter is exactly the kind of improvement these patients need. The Phase 3 results we shared at VAM tell a clear, compelling, and consistent story."

Patients on dialysis need a reliable, long-lasting connection to their bloodstream so a machine can draw out blood, clean it, and return it. The most common approach today is an AV fistula, a connection a surgeon creates between an artery and a vein. But AV fistulas often fail to develop the way they should, especially in women. When that happens, patients rely on catheters, tubes placed in the body that carry a high risk of infection.

In the V012 study, women who received the ATEV were able to avoid catheter use three months longer than women who received the standard of care. Over the first year, women with the ATEV averaged 220 days free of a catheter, compared with 129 days for women who received an AV fistula, and the difference was statistically significant (p=0.00070). Infections were also less common in patients receiving the ATEV: patients had about 6 infections per 100 patient years, compared with 23 per 100 patient years for patients who received an AV fistula. None of the infections in the ATEV group were tied to the blood vessel itself, compared with three in the fistula group, and no ruptures occurred in either group.

"Fistulas often fail to develop in women, which forces too many patients to rely on catheters and risk the infections that often come with them," said Mohamad A. Hussain, MD, PhD, a vascular and endovascular surgeon-scientist at Heart and Vascular Institute, Mass General Brigham and Associate Professor of Surgery at Harvard Medical School. "An option that is ready to use off the shelf and that keeps patients off catheters will fill a real gap in how we care for these patients today."

In V012 the ATEV was also observed to have consistent advantages over AV fistula in the secondary efficacy endpoints for the study. Six-month catheter-free days averaged 88 days for ATEV compared to 32 days for AV fistula (p=0.00009). Functional patency over 12 months averaged 250 days for ATEV compared to 152 days for AV fistula (p=0.00057). Six-month secondary patency was 87.5% for ATEV compared to 65.0% for AV fistula (p=0.0013). Twelve-month secondary patency was 77.5% for ATEV compared to 62.5% for AV fistula (p=0.16).

"Time on a catheter is time at risk, so keeping patients catheter-free for longer really matters," added Young M. Erben, MD, a vascular surgeon at Mayo Clinic in Jacksonville, Florida, and Professor of Surgery at Mayo Clinic College of Medicine and Science. "A dependable, readily available access option could be especially valuable for women and others who are not good candidates for a fistula."

The safety profile in both groups was comparable, with the ratio of all adverse events reported below adjusted for patient years of use. Serious adverse events were 1.73 for ATEV compared to 4.77 for AV fistula. Adverse events of special interest (AESI) were 2,71 for ATEV compared to 3.88 for AV fistula. Within AESIs, thrombotic events were 0.75 for ATEV compared to 0.51 for AV fistula, and 75.0% of ATEV thrombosis cases successfully resolved compared to 37.5% for AV fistula. Stenotic events were 1.62 for ATEV compared to 2.29 for AV fistula.

In accordance with the study protocol, as a result of meeting the primary superiority endpoint of catheter-free days, 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.

Humacyte will host an investor event today, June 15, 2026 at 5:00 p.m. ET to discuss the V012 Phase 3 results and what they mean for patients, with registration information listed below.

Registration information	**Q&A information**
You are required to register in advance for the event. For those who are unable to attend live, a replay will be available by **clicking here.**	If you would like to ask a question during the live Q&A, please submit your request to **questions@lifesciadvisors.com**.

Reporters interested in an interview with Humacyte leadership about the V012 results should contact Rich Luchette at rich@precisionstrategies.com.

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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