Humacyte Acellular Tissue Engineered Vessel (ATEV™) Meets Primary Endpoints in V007 Phase 3 Clinical Trial in Arteriovenous Access for Hemodialysis

– ATEV demonstrated superiority at six and 12 months (co-primary endpoints) compared to autogenous fistula, the current standard of care for hemodialysis –

– Detailed results to be presented at upcoming medical conferences –

DURHAM, N.C., July 31, 2024 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced positive top-line results from the V007 Phase 3 Clinical Trial of the acellular tissue engineered vessel (ATEV) in arteriovenous access for patients with end-stage renal disease. In the Phase 3 trial, the ATEV demonstrated superior function and patency at six and 12 months (co-primary endpoints) compared to autogenous fistula, which is the current standard of care for hemodialysis patients.

"We are thrilled to announce positive results for the Phase 3 V007 trial, which we believe highlight the potential of the ATEV to improve AV access in hemodialysis patients who are underserved by the current standard of care," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "Achievement of this major milestone has taken a tremendous amount of effort and commitment from our patients, clinical investigators, employees, and other collaborators, and I thank them for their great support and contributions. We expect to discuss a potential market authorization pathway for the ATEV in hemodialysis access with the Food and Drug Administration soon. We also look forward to presenting more detailed results from the study, including subgroup analysis results, at upcoming medical conferences."

The V007 Phase 3 trial (NCT03183245) is a prospective, multi-center, randomized clinical study in 242 hemodialysis patients in the United States. gEnrolled individuals were randomly assigned to receive either the ATEV or an arteriovenous (AV) fistula for hemodialysis access and are bein 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. At six months, 81.3% of the patients implanted with the ATEV had functional patency compared to 66.4% of the patients receiving an AV fistula. At 12 months, 68.3% of the patients implanted with the ATEV had secondary patency, compared to 62.2% of the patients receiving an AV fistula. The joint test for superiority of the ATEV versus AV fistula at six and 12 months was statistically significant (p=0.0071). Patients on ATEV also achieved a significantly longer duration of hemodialysis over the first 12 months, as compared to autogenous fistula (p=0.0162). More adverse events were reported in patients on the ATEV treatment arm than those on the AV fistula treatment arm.

Nearly 808,000 Americans are currently living with end-stage renal disease, a medical condition that develops when chronic kidney disease progresses to a point where either dialysis or a kidney transplant is required 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. But 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 infection, while autogenous AV fistulas often fail to function, 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 designed to be a universally implantable vascular conduit for use in vascular replacement and repair, and for use as hemodialysis access. The ATEV has been observed to have a low rate of infection in 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. As announced previously, based on guidance from the FDA, the proper or generic (non-brand) name "acellular tissue engineered vessel" (ATEV) has replaced the term "Human Acellular Vessel" (HAV) that was previously used for our bioengineered vessel candidate.

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 initial product candidates, a portfolio of ATEVs, are currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous (AV) access for hemodialysis, and peripheral artery disease. A Biologics License Application for the ATEV in the vascular trauma indication is currently under review by the FDA and was granted Priority Review with a PDUFA date of August 10, 2024. 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 an 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, the expected PDUFA date for our ATEV in vascular trauma repair; the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials, including our BVP program; the anticipated characteristics and performance of our ATEVs and the BVP; our ability to successfully complete, preclinical and clinical trials for our ATEVs and the BVP; the anticipated benefits of the BVP relative to existing alternatives; the anticipated commercialization of our ATEVs and our ability to manufacture at commercial scale; 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, and/or competitive 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, 2023, 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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