Humacyte Clinical Results Highlighting Benefit of the ATEV™ in the Repair of Civilian and Military Arterial Injuries Published in JAMA Surgery

– In two studies the acellular tissue engineered vessel (ATEV) provided benefits in terms of patency, limb salvage, and infection resistance compared to current synthetic graft treatment benchmarks –

– Results were published in a premier peer-reviewed surgical journal sponsored by the American Medical Association –

DURHAM, N.C., Nov. 21, 2024 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced the publication of clinical results evaluating the efficacy and safety of the acellular tissue engineered vessel (ATEV) in the repair of extremity civilian and military injuries in *JAMA Surgery*, an American Medical Association peer-reviewed journal. The publication “Bioengineered Human Arteries for the Repair of Vascular Injuries” describes two clinical studies in which the ATEV demonstrated benefits in terms of patency (blood flow), limb salvage, and infection resistance compared to synthetic graft benchmarks in the treatment of acute vascular injuries of the extremities.

“The development of a vascular conduit that resists infection and remodels into native arteries is an extraordinary technological advancement that will have a huge impact on the quality of trauma care around the world,” said Charles J. Fox, MD, FACS, Director of Vascular Surgery at the University of Maryland Capital Region, a clinical investigator in the Humacyte V005 trauma clinical trial. “The ATEV is perfectly sized to treat most injuries, has excellent handling properties, and reduces time necessary to save both life and limbs. Finally, an innovative technology has been developed for battlefield vascular injuries using a tissue engineered human arterial replacement that can resist infections that are so prevalent in modern combat zones. The ATEV shows promise to reduce amputation rates since an alternative conduit for war injuries is often needed but up until now has not been a good option.”

The *JAMA Surgery* publication described the results of two studies in which the ATEV was evaluated in patients with extremity vascular trauma. The V005 clinical trial was a single-arm study conducted in the United States and Israel in patients with arterial injuries resulting from gun shots, workplace injuries, car accidents, or other traumatic events for whom the standard of care, saphenous vein, was not feasible or available to use as a bypass graft. The V017 single-arm clinical trial evaluated patient outcomes from a humanitarian program which patients with wartime injuries were treated in Ukraine. As single-arm studies, the comparators for the ATEV results were a systematic literature review and meta-analysis of studies conducted with synthetics grafts, providing a current treatment benchmark comparison. In a meta-analysis combining the V005 and V017 trials, the ATEV demonstrated higher patency with a 30-day secondary patency rate of 91.5% for the extremity patients compared to 78.9% historically reported for synthetic grafts. For the secondary comparison of amputation rates, the ATEV demonstrated an improvement with a rate of 4.5% for extremity patients compared to 24.3% historically reported for synthetic grafts. For the secondary comparison of infection, the ATEV demonstrated an improvement with a reduced rate of 0.9% for the extremity patients compared to 8.4% historically reported for synthetic grafts. In summary, researchers concluded that the 30-day outcomes in civilian and military trauma patients indicate superior secondary patency, limb salvage, and resistance to infection of the ATEV conduit compared to synthetic grafts.

"I believe that the ATEV will revolutionize vascular trauma care and be profoundly beneficial to our patients," said Rishi Kundi, MD, Chief of Vascular and Endovascular Trauma at the University of Maryland's R Adams Cowley Shock Trauma Center. "Based on my personal experience so far, the ATEV will allow reconstruction that is currently impracticable because of contamination or infection; moreover, it will make reconstruction that we are now forced to perform with prosthetic or even biologic grafts more successful. I am excited about the promise that the ATEV holds for the long-term experience and outcomes of our patients."

Also published were longer-term follow-up results from the V005 and V017 studies. The ATEV was observed to be mechanically durable and does not appear to dilate or become stenotic over time. Long-term outcomes for secondary patency, limb salvage, freedom from conduit infection, and patient survival were evaluated by Kaplan-Meier analysis. The average follow-up duration for patients receiving the ATEV for extremity trauma is 334.4 days, with a total patient exposure of 61.3 years. These results showcased the potential of the ATEV to retain patency over the longer duration of follow up. No ATEV infections or patient deaths were reported after month three.

“If approved by the FDA, the ATEV will be the preferred conduit for complex extremity vascular injuries, and particularly those at risk for infection.” said Ernest E. Moore, MD, FACS, Director of Research at the Ernest E. Moore Shock Trauma Center at Denver Health, a clinical investigator in the V005 trial. “I look forward to the ATEV being available for use in my practice.”

Evaluation of the safety of the ATEV indicated no safety signals attributable to ATEV mechanical weakness, contamination, or immune rejection. Overall, Adverse Events (AEs) and Serious Adverse Events (SAEs) were consistent with patients suffering from acute injuries. Adverse Events of Special Interest (AESIs) including thrombosis, rupture, aneurysm, and pseudoaneurysm, occurred at rates that were consistent with reports of other vascular conduits, including autologous vein and synthetic grafts. The meta-analysis combing the V005 and V017 trials showed a 30-day rate of death in ATEV patients of 3.5%, comparable to the 3.4% rate historically reported for synthetic grafts. There were no deaths attributable to the ATEV.

The ATEV is an investigational, first-in-class bioengineered human tissue that is designed to be a universally implantable vascular conduit for use in arterial replacement and repair, and for use as hemodialysis access. While harvesting vein from a trauma patient requires critical surgical time, the ATEV is designed to be available immediately, off-the-shelf. A Biologics License Application for the ATEV in a vascular trauma indication is currently under review by the U.S. Food and Drug Administration (FDA).

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. Humacyte 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. 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 statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our ATEV; our ability to successfully complete preclinical and clinical trials for our ATEVs; the anticipated benefits of the our ATEVs 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, our quarterly report on Form 10-Q for the quarter ended September 30, 2024, each filed by Humacyte with the SEC, and in subsequent 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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