Humacyte Announces Publication of Biological Mechanism Explaining Low Rates of Infection Observed in Clinical Study of Human Acellular Vessel™ (HAV ™)

Results published in Journal of Vascular Surgery – Vascular Science

DURHAM, N.C., Aug. 03, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announces the publication of controlled *in vitro* studies in the *Journal of Vascular Surgery – Vascular Science* describing the scientific basis for the significantly lower rates of infection observed in a clinical trial of the investigational HAV compared to synthetic expanded polytetrafluoroethylene (ePTFE) grafts. The *in vitro* study results show the HAV had more host cell infiltration than ePTFE grafts, and that the biocompatibility of the HAV supported neutrophil viability and function, each of which may explain the HAV's superior resistance to bacterial infection versus ePTFE grafts observed in the clinical trial.

The publication, titled *Biological Mechanisms of Infection Resistance in Tissue Engineered Blood Vessels Compared to Synthetic ePTFE Grafts*, combined histological evaluation of the HAV and ePTFE explants from both preclinical and clinical studies as well as *in vitro* experiments assessing the viability and function of human neutrophils on these materials. Neutrophils are a critical cell type for host defense against infection. Data analyzed from a comparative clinical trial demonstrated that the HAV had a significantly lower infection rate than ePTFE grafts. A biological rationale for this finding was then shown through explant histopathology and cell experiments which demonstrated that the HAV, but not ePTFE grafts, supported neutrophil viability and function. These results continue to build upon the functional benefits of HAV biocompatibility which has been previously observed to permit adaptive host vascular remodeling and now host immune activity for infection resistance.

"This study further supports that the HAV has the potential to serve as a breakthrough treatment to save the lives and limbs of patients suffering from a wide range of medical conditions, from trauma to peripheral artery disease," said Dr. Laura Niklason, CEO of Humacyte. "Our goal is to provide a solution that overcomes the current limitations in existing standards of care, in this case remembering that vascular graft infection can be a devastating and costly outcome for patients already suffering from severe and complex conditions."

Vascular graft infection represents a significant clinical and economic burden in the United States, with a tremendous impact on patient quality of life and an estimated cost of over $1 billion per year. Complications of infection can include amputation, sepsis, and death. Synthetic vascular grafts, such as those constructed from ePTFE, suffer from infection rates as high as 28% when used for dialysis access and between 20-35% when used in vascular trauma repair.

The HAV has accumulated over 1,000 patient-years of experience worldwide in a series of clinical trials in multiple indications, including vascular trauma repair, arteriovenous access for hemodialysis, and peripheral artery disease.

The HAV 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 opportunity, a portfolio of HAVs, is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, AV access for hemodialysis, and peripheral arterial disease. 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 HAV 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 HAV for urgent arterial repair following extremity vascular trauma also has received RMAT designation. The HAV 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, statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our HAVs; our ability to successfully complete, preclinical and clinical trials for our HAVs; the anticipated benefits of our HAVs relative to existing alternatives; the anticipated commercialization of our HAVs and our ability to manufacture at commercial scale; the implementation of our business model and strategic plans for our business; the timing or likelihood of regulatory filings and approvals; timing, scope, and rate of reimbursement for our HAVs; the outcome of our ongoing discussions with the FDA concerning the design of our ongoing V005 Phase 2/3 clinical trial, including determination of trial size, and the scope of any approved indication for our HAVs; and our estimated available market opportunity. 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 included under the header "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, 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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