Results From Mayo Clinic Clinical Study of Humacyte's Human Acellular Vessel™ (HAV™) in Treatment of Patients with Chronic Limb Ischemia Presented at Midwestern Vascular Conference

-Researchers concluded that in the clinical study the HAV was a safe, resilient, and effective conduit for arterial bypass and limb salvage-

DURHAM, N.C., Sept. 11, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced the presentation of results from a Food and Drug Administration (FDA)-regulated, investigator-sponsored clinical study conducted at the Mayo Clinic. In the study the investigational HAV is being evaluated in patients with chronic limb-threatening ischemia (CLTI), the end stage of peripheral artery disease (PAD). The presentation at the Midwestern Vascular Conference in Minneapolis, MN, entitled *Outcomes of Arterial Bypass Using the Human Acellular Vessel (HAV) In Patients With Chronic Limb Threatening Ischemia*, concluded that in the clinical study the HAV was a safe, resilient, and effective conduit for arterial bypass and limb salvage. This is an important result since approximately 40% of patients requiring lower extremity bypass do not have saphenous vein available, which is the standard of care for treating this challenging disease state.

The presentation reported the outcomes of 29 patients, with a mean age of 71 and having no available vein to use as a bypass graft, who underwent HAV implantation. Of these 29 patients, 97% had previously experienced unsuccessful revascularization procedures on the extremity and 21 (72%) had tissue loss or gangrene. Based on the state of this disease, this patient group had a 30-50% one-year risk of amputation. Notably, surgery in 22 (76%) patients necessitated a tibial artery target, a surgical procedure involving the fusion of two 42 cm long HAVs to achieve the required bypass length. Surgeons reported that the operations to implant the HAV achieved a 100% technical success rate, without any HAV-related major adverse events reported. At a median follow-up of nine months, the secondary patency rate for patients implanted with the HAV was 72%. The limb salvage rate was 86%, corresponding to only a 14% amputation rate.

"Millions of individuals suffering from PAD today deserve treatment options that are not only effective, but that reduce unnecessary pain and suffering," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "The results of this Mayo Clinic clinical study demonstrate the potential of the HAV to bridge existing gaps in treatment and provide an alternative that is ready off-the-shelf for surgeons to use to help prevent the loss of limb and life."

PAD is increasingly prevalent, affecting approximately one in every 20 Americans over the age of 50. CLTI is an advanced, severe form of PAD that poses a significant risk to limb health and viability. CLTI occurs when blood flow to the limbs, usually to the legs and feet, is severely compromised due to the blockage of arteries. Restricted blood flow can lead to tissue damage, ulcers, and even gangrene–characterized by pain and open sores – and a high risk of amputation in the absence of medical intervention. Traditional treatment involves bypass surgery, which uses the saphenous vein to restore proper blood flow to the limbs. However, approximately 40% of patients lack a suitable vein for bypass, and surgical vein removal, even when possible, carries associated risks including infection, nerve damage, and blood clots.

The HAV, a bioengineered tissue, is under investigation as an infection-resistant alternative for revascularization. Designed to be ready off-the-shelf, the HAV has the potential to save valuable time for surgeons and to reduce discomfort and complications for patients. Importantly, the HAV can be produced at commercial scale in Humacyte's existing manufacturing facilities, providing thousands of vessels for treating patients in need. The HAV has accumulated more than 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 PAD.

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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