Humacyte Presents Clinical Performance of Human Acellular Vessel™ (HAV™) From Ukrainian Humanitarian Program

-Clinical outcomes presented at Military Health System Research Symposium (MHSRS)-

-Results will be included in Biologics License Application (BLA) planned for fourth quarter 2023-

DURHAM, N.C., Aug. 15, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, presented yesterday at MHSRS the clinical results of a year-long humanitarian program in Ukraine. The Company's investigational Human Acellular Vessel (HAV) was provided to five hospitals on the frontlines to treat traumatic vascular injuries beginning in June 2022.

War injuries in Ukraine have led to tens of thousands of amputations, many of which occur because blood flow cannot be restored after the injury. As of July 2023, the HAV has been used to treat 19 patients in Ukraine suffering from a range of traumatic vascular injuries, including gunshots, shrapnel, blasts, and industrial accidents. Clinicians reported that the rate of success in treating patients with the HAV was high, with an observed 30-day HAV patency (presence of blood flow) of 95%. At 30 days after treatment with the HAV, the limb salvage rate was 100%, meaning no amputations occurred in patients treated with the bioengineered vessel. In addition, there was 100% patient survival and no cases of infection of the HAV. There was one patient whose HAV had to be removed due to shrapnel-related bleeding.

"The HAV demonstrates enormous promise for treating critical injuries, both in overseas conflicts and civilian settings here at home," said Laura Niklason, CEO of Humacyte. "We remain dedicated to partnering with healthcare providers and regulatory authorities to make this groundbreaking technology accessible to the patients and surgeons who need it most."

"The most expensive thing in life, in love, in war, and in limb-saving vascular reconstruction is time," said Oleksandr Sokolov, M.D., Ph.D., a Ukrainian vascular surgeon and HAV implanter in the humanitarian program. "The novel bioengineered, off-the-shelf HAV provides time to the surgeon and patient. It has the potential to be a significant advancement in treating life-threatening combat vascular injuries."

Humacyte's humanitarian program was initiated in May 2022, when the company provided investigational HAVs to hospitals in Vinnytsia, Dnipro, Odessa, Kyiv, and Kharkiv, in response to Ukrainian surgeon requests. Humacyte worked closely with the International Office of the U.S. Food and Drug Administration (FDA) and the Ukrainian Ministry of Health to obtain approval for the program. Humacyte then subsequently trained Ukrainian surgeons by video conference on how to implant the HAV.

The HAV, an innovative regenerative medicine product candidate, is designed to provide surgeons with a universally implantable, bioengineered human vessel. It is intended to be available to the surgeon immediately and provide a potentially life and limb saving option in circumstances where synthetics are not indicated and autologous vein is not feasible. Designed to be off-the-shelf, the HAV has the potential to save valuable time and reduce complications like amputations and tissue loss. Additionally, the HAV is comprised of the same tissue that makes up natural human vessels, thereby having the potential to repopulate with the patient's own cells. Clinical results suggest that the HAV is durable and highly infection-resistant, and therefore may be well suited for treating the contaminated wounds created by major wartime blast and shrapnel injuries. Importantly, the HAV can be produced at commercial scale in Humacyte's existing manufacturing facilities, providing thousands of vessels for treating injured patients.

The new data demonstrating the HAV's success on the frontlines in Ukraine will be included as part of the data in the Humacyte's Biologics License Application (BLA) to the FDA, which is planned for fourth quarter 2023. The planned BLA will build on results from Humacyte's pivotal trial studying the HAV in treating patients with vascular injury in the extremities, which recently completed enrollment. The HAV also received the FDA's Regenerative Medicine Advanced Therapy (RMAT) designation in May 2023 for urgent arterial repair following extremity vascular trauma. The RMAT designation allows for close collaboration between Humacyte and the FDA during the application process.

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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