Humacyte Announces Presentation on Investigational Human Acellular VesselTM for Treatment of Vascular Trauma at the International Committee of Military Medicine World Congress

September 9, 2022

Dr. Todd E. Rasmussen provides HAV™ clinical update and surgical skills workshop at ICMM

DURHAM, N.C., Sept. 09, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissues, complex tissue systems, and organs at commercial scale, today announced the presentation of a clinical update on the Human Acellular Vessel (HAV) for the treatment of vascular trauma. The HAV is designed to offer off-the-shelf availability and resistance to infection, as well as to address long-standing limitations in vascular tissue repair and replacement. The update was presented by Todd E. Rasmussen, M.D., FACS, (Col, ret. USAF MC), at the 44th International Committee of Military Medicine (ICMM) World Congress in Brussels, Belgium.

Speaking to an audience of NATO and other international surgeons, Dr. Rasmussen reported that over the past several decades the incidence of wartime vascular injury has increased. Dr. Rasmussen added that vascular injury, whether in a military or civilian setting, is a leading cause of death and or amputation. Dr. Rasmussen's presentation highlighted the clinical progress of the HAV, including updates on his own experiences and those of his colleagues utilizing the vessel to treat patients, as well as the potential of the investigational product to overcome limitations in care. According to Dr. Rasmussen's conclusions, injured service members and those with certain complex injuries in the civilian sector could benefit from the use of a readily available and infection resistant vascular conduit that would facilitate quick implantation and restoration of blood flow, even in the setting of contaminated wounds such as those encountered on the battlefield.

"The incidence of vascular trauma in the modern combat setting has increased 5-fold over the past century. Advances in pre-hospital casualty care now allow surgeons to attempt repair and limb salvage in 2/3rds of these cases. Because most injuries are the result of blast injuries and are associated with soft tissue wounds and contamination, there is a pressing need for a readily available, infection-resistant biologic conduit for arterial repair or bypass." said Dr. Rasmussen. "Currently available synthetic conduits such as plastic and polyester grafts, and even cryopreserved allografts, are not practical or durable in these settings. The HAV has the physical and biologic properties to be an ideal solution for wartime vascular injury, and even many injuries sustained in the civilian setting."

Humacyte's investigational HAVs were recently provided as part of a humanitarian relief effort to several front-line Ukrainian hospitals, allowing doctors the opportunity to utilize the HAVs to treat patients with traumatic vascular injuries during the conflict. Patients successfully treated to date under the humanitarian program include those with a range of traumatic injuries, including those from gunshots, shrapnel, and industrial accidents. Humacyte is working closely alongside the Office of International Programs within the U.S. Food and Drug Administration (FDA) and the Ukrainian Ministry of Health as the humanitarian efforts in Ukraine progress, and the company continues to provide this additional treatment option to those affected.

Laura Niklason, M.D., Ph.D., chief executive officer of Humacyte, added, "We have already observed the HAV to be durable and infection resistant in multiple clinical trials. Being able to provide our investigational vascular conduit as part of the humanitarian relief initiative is a great honor for us, as we work together with the skilled physicians, nurses, and staff to save the lives and limbs of those involved in the conflict."

Humacyte's HAVs are engineered off-the-shelf replacement vessels and are currently being evaluated in multiple advanced-stage clinical trials in vascular trauma repair, arteriovenous access for hemodialysis and peripheral arterial disease. Under eight clinical trials, and combined with the FDA's Expanded Access Program (EAP), the HAV has been implanted in more than 500 patients to date. The HAV is an investigational product and has not been approved by the FDA, the Ukrainian Ministry of Health, or any international regulatory agency.

About HAV
Human Acellular Vessels (HAV) are investigational engineered off-the-shelf replacement vessels initially being developed for vascular repair, reconstruction and replacement. HAV is intended to overcome long-standing limitations in vessel tissue repair and replacement – it can be manufactured at commercial scale, it eliminates the need for harvesting a vessel from a patient, and clinical evidence suggests that it is non-immunogenic, infection-resistant, and can become durable living tissue. The HAV is currently being evaluated in two Phase 3 trials in arteriovenous access and a Phase 2/3 trial for vascular trauma, and has been used in more than 500 patient implantations. Humacyte's 6mm HAV for AV access for performing hemodialysis was the first product to receive Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA), and has also received FDA Fast Track designation. The HAV has received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense.

About Humacyte
Humacyte, Inc. (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues and complex tissue 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 human acellular vessels (HAVs), is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous 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 arteriovenous (AV) access for performing 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. 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 benefits and risks related to our humanitarian efforts in the Ukraine; 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; our rights and obligations under our partnership with Fresenius Medical Care; the scope of protection we are able to establish and maintain for intellectual property rights covering our HAVs and related technology; the timing or likelihood of regulatory filings and approvals; timing, scope, and rate of reimbursement 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, the impact of COVID-19 on Humacyte’s business, 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, 2021, 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. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. 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.

Humacyte Investor Contact:
Joyce Allaire
LifeSci Advisors LLC
+1-617-435-6602
jallaire@lifesciadvisors.com
investors@humacyte.com

Humacyte Media Contact:
Elizabeth Miller, M.D.
LifeSci Communications LLC
+1-646-791-9705
emiller@lifescicomms.com