Humacyte Announces Publication Highlighting the First Use of the Human Acellular Vessel (HAV ™) as Arterial Bypass Conduit for Replacement of Infected Prosthetic Graft

December 15, 2021

-- Vanderbilt University Medical Center patient received the HAV under the U.S. Food and Drug Administration's (FDA) Expanded Access Program (EAP) in April 2019 --

-- After replacement, the patient resumed regular physical activity with no signs of infection of the HAV implant observed --

-- Published in Journal of Vascular Surgery: Cases, Innovations and Techniques --

-- HAV used in 20 EAP cases to date, for treatment of severe vascular disease and trauma --

DURHAM, N.C., Dec. 15, 2021 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced that results from a case study of a patient who received the human acellular vessel (HAV) as a replacement for an infected synthetic iliofemoral bypass graft have been published online in the *Journal of Vascular Surgery: Cases, Innovations and Techniques* (JVSCIT). The manuscript, entitled "Surgical management of an infected external iliac artery interposition graft with a bioengineered human acellular vessel," reports the first use of the HAV in the treatment of a patient with an infected prosthetic vascular graft, a procedure performed in April 2019 under an expanded access use authorized by the FDA.

The case report describes a 42-year-old female patient with a medical history of a right external iliac artery endofibrosis (EIAE) who had ipsilateral claudication and a persistently infected synthetic iliofemoral bypass graft replaced with a bioengineered HAV. Twenty-two months post-implantation, the patient demonstrated significant clinical improvement and had resumed regular physical activity. In addition, no signs of infection of the HAV implant have been observed. The patient's story can be viewed here: https://www.youtube.com/watch?v=-bRPYKzO5B8.

"Very few techniques exist that provide durable long-term or permanent solutions to vascular reconstruction," said Thomas Naslund, M.D., of Vanderbilt University Medical Center and co-author on the case study. "The potential of the investigational HAV to populate with the patient's own cells and become a part of the patient's own DNA and own tissue, and thereby be durable over time and free from complications that threaten other types of conduits, warrants further evaluation as a replacement for infected synthetic vascular grafts."

"While the HAV is being evaluated in multiple international multicenter clinical trials in vascular trauma, arteriovenous access for dialysis, and peripheral arterial disease (PAD), with over 460 HAV implants to date and more than 900 years of cumulative patient exposure, this was the first use of the HAV to replace an infected synthetic graft," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "We are pleased that the HAV has continued to function in this patient over an extended period of time. The challenging cases experienced under the EAP program continue to show the potential of our bioengineered tissue platform to redefine what's possible in regenerative medicine."

The case report can be accessed at https://www.sciencedirect.com/science/article/pii/S2468428721001763.

The patient received the HAV, following approval of the EAP from the FDA, at the Vanderbilt University Medical Center. The HAV has been used in other EAP cases for patients with peripheral arterial disease (PAD) and vascular trauma, for which there are limited treatment options. In October, the Mayo Clinic in Rochester, Minn. filed an Investigational New Drug application #27864 with FDA. This IND will allow Mayo Clinic surgeons access to the investigational HAV for treatment of severe PAD in up to 25 patients who lack options for surgical bypass to restore adequate blood flow to the leg, which if left untreated can lead to amputation. The HAV is an investigational product candidate and is not currently approved for sale by the FDA or any international regulatory authority. For more information on Humacyte's EAP for HAV, visit https://humacyte.com/expanded-access-policy/.

About HAV
Human Acellular Vessels (HAV) are 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. 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 460 patient implantations. It is 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.

About Humacyte
Humacyte, Inc. (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues and organs 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. Pre-clinical 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 HAVs were the first product to receive the FDA's Regenerative Medicine Advanced Therapy (RMAT) expedited review designation and 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 clinical trials; the anticipated characteristics and performance of our HAVs; our ability to successfully complete pre-clinical 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; 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 the registration statement on Form S-1 filed by Humacyte with the SEC, as updated by any subsequent Form 10-Qs, Form 10-Ks and Form 8-Ks that we may file with the SEC. 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:
investors@humacyte.com

Humacyte Media Contact:
media@humacyte.com