



Humacyte Announces Presentation of First Eight Expanded Access Cases Using Human Acellular Vessel™ (HAV) for Treatment of Critical Limb Ischemia at 46th Annual Winter Meeting of the Vascular and Endovascular Surgery Society

DURHAM, N.C., Jan. 06, 2022 (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 the first series of compassionate use cases of Humacyte's Human Acellular Vessel™ (HAV) will be presented at the 46th Annual Winter Meeting of the Vascular and Endovascular Surgery Society (VESS) in Snowmass, Colo. at 7:56 a.m. MST on January 28, 2022. The presentation will describe the outcomes of HAV implantation into eight patients for the treatment of critical limb ischemia, under the U.S. Food and Drug Administration's (FDA) Expanded Access Program (EAP). The presentation, titled "Real World Experience with the Human Acellular Vessel: A Bioengineered Implant for Arterial Repair That Expands Limb Salvage Options," will be made by Alexander Kersey, M.D., of the Uniformed Services University of the Health Sciences and Walter Reed National Military Medical Center in Bethesda, MD.

Humacyte's HAVs are engineered off-the-shelf replacement vessels that are currently being evaluated in late-stage clinical trials in vascular trauma repair, arteriovenous access for hemodialysis, and peripheral arterial disease (PAD). The HAV has been used in EAP cases for patients with severe PAD and vascular injury for whom there are limited treatment options. The VESS presentation will highlight eight HAV implantations in patients with PAD or vascular injury who had exhausted other treatment options and would have otherwise faced amputation and limb loss.

"Vascular reconstruction remains a critical need for successful limb salvage. Many patients have limited options for revascularizing their severely ischemic limbs, and we are developing the HAV to potentially offer an immediate option for difficult revascularization scenarios," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "This will be the first time that results from our use of the HAV for limb salvage have been reported, and we're looking forward to Dr. Kersey's presentation at VESS."

The Annual Meeting of the VESS brings together internationally recognized, fellowship-trained vascular surgeons, and provides the premiere forum to promote the field of vascular and endovascular surgery through education, advocacy and leadership. For more information, visit <https://vesurgery.org/meetings/winter/>.

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. 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 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, 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; 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, as amended, filed by Humacyte 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.

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