Humacyte Preclinical Data on Small-Diameter Human Acellular Vessel™ (HAV™) in Coronary Artery Bypass Grafting (CABG) Presented at American Heart Association Meeting

-- Preclinical model data expected to support development of small diameter HAV to treat patients with coronary artery disease--

-- Small-diameter HAV observed to maintain patency and exhibit host-cell remodeling at six months post-implantation in a non-human primate model–

--Results presented at American Heart Association Basic Cardiovascular Sciences Scientific Sessions 2022 --

DURHAM, N.C., July 25, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced results evaluating the use of the small-diameter (3.5mm) Human Acellular Vessel (HAV) for coronary artery bypass grafting (CABG) in a non-human primate model. The HAV was observed to maintain structural integrity and patency for up to six months post-implantation and showed evidence of robust host cell repopulation and remodeling. The results were presented by Adam Williams, M.D., cardiothoracic surgeon, Duke University, at the American Heart Association Basic Cardiovascular Sciences Scientific Sessions (BCVS) 2022 in Chicago, IL on July 25, 2022, and will be published in the September issue of Circulation Research.

Humacyte's HAVs are engineered replacement vessels designed to be durable, infection-resistant and off-the-shelf to address long-standing limitations in vessel tissue repair and replacement. CABG surgery, which treats the blockage of the coronary arteries to restore blood flow to the heart, is performed more than 400,000 times annually in the United States, with over 765,000 annual CABG procedures globally. Humacyte is developing a small-diameter HAV as a potential alternative to existing vascular conduit substitutes during CABG surgery, particularly in obese or diabetic patients, where the risks of saphenous vein harvesting are substantial.

“CABG is one of the most common surgical procedures, and we are often limited by our ability to find suitable conduit. Saphenous vein grafts are used in 80-90% of CABG procedures, with variable vein quality among patients, and have been shown to fail in up to one-third of patients within one year. In addition, vein harvesting is associated with an increased risk of infection and pain,” said Dr. Williams. “The results presented yesterday from a preclinical model demonstrate that tissue-engineered HAVs may provide an off-the-shelf conduit for CABG, potentially eliminating the need for vein harvesting, and support the continued evaluation of the safety and durability of the small-diameter HAV as a conduit for CABG.”

In the preclinical study, CABG surgery was performed using small-diameter HAVs implanted into seven non-immunosuppressed, non-human primates following ligation of the proximal coronary artery. The study focused on development of a non-human primate model under which the HAV could be reliably implanted. In two animals, the HAV maintained patency and the heart was functional throughout a six-month period, as observed by angiography performed at two weeks, and at one, three and six months. In these animals, the HAV was explanted at six months and histology revealed infiltration of multiple host cell populations, including adventitial, smooth muscle and endothelial cell types, that remodeled the HAV. The HAVs exhibited structural integrity and there was no evidence of mechanical failure during the study.

“We’re pleased that data on our small-diameter HAV program in CABG have now been presented at two preeminent scientific conferences, Advanced Therapies Week and the American Heart Association’s Basic Cardiovascular Sciences Scientific Sessions. In this study, the HAV was observed to maintain patency and function and showed vascular host-cell repopulation, which are qualities we’ve consistently observed in our 6mm HAV across multiple late-stage trials in vascular applications,” Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. “Moreover, the study provides more insight on the surgical model, which will support our continued evaluation of the HAV in CABG as we move toward planned human clinical studies.”

The HAV is currently being evaluated in late-stage clinical trials in vascular trauma repair, AV access for hemodialysis, and peripheral arterial disease. The HAV is an investigational product candidate and is not currently approved for sale by the FDA or any international regulatory authority.

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 nearly 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 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:
media@humacyte.com