Humacyte Announces Preclinical Results of Small-Diameter Human Acellular Vessel™ (HAV™) in Coronary Artery Bypass Grafting

January 28, 2022

-- HAV remained patent and host-cell remodeling was observed in non-human primate model --

-- Preclinical study represents milestone in the development of small-diameter HAVs for use in cardiac bypass surgery --

-- Results presented at Advanced Therapies Week 2022 --

DURHAM, N.C., Jan. 28, 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 from the first preclinical study of the use of Humacyte's small-diameter (3.5mm) Human Acellular Vessel (HAV) in coronary artery bypass grafting (CABG), which were presented at Advanced Therapies Week. The HAV maintained patency and exhibited host-cell remodeling and regeneration in a non-human primate model.

CABG, performed approximately 400,000 times each year in the U.S., is a surgical procedure where a vascular graft is placed to bypass occluded coronary arteries and restore blood flow to the heart. Saphenous vein grafts are used in 80-90% of CABG procedures but have shown a 30% failure rate at one year.

In the preclinical study, the 3.5mm HAVs were implanted into primates following ligation of the native right coronary artery, and the primates were studied for six months. The HAVs that have been examined to date, one being explanted at six months, remained patent and vascular host-cell repopulation was observed. The preclinical surgeries were performed by Alan P. Kypson, M.D., cardiothoracic surgeon, University of North Carolina Rex Hospital, and Adam Williams, M.D., cardiothoracic surgeon, Duke University, in collaboration with Duke's Division of Laboratory Animal Resources and Department of Surgery.

"Coronary artery bypass grafting is one of the most common surgical procedures in the U.S., but it currently requires surgically harvesting a saphenous vein for grafting. The quality and availability of the venous conduit is a critically important factor in a successful CABG and the potential to eliminate vein harvesting with a universally implantable, readily available acellular vessel is exciting," said Dr. Kypson, who presented the results today. "Results observed in this preclinical study indicated the small-diameter HAV was an effective replacement vessel for CABG surgery in baboons, a primate that is phylogenically similar to humans, which supports the continued investigation of HAV in CABG." Dr. Kypson has led the large animal preclinical development of Humacyte's vessels in CABG for more than a decade.

Humacyte plans to evaluate the safety and efficacy of these small-diameter HAVs in additional preclinical primate CABG studies designed to support first-in-human clinical trials. The 3.5mm diameter HAV has smaller product dimensions but is manufactured using a similar process as Humacyte's 6mm HAV system currently being evaluated in advanced-stage clinical trials in vascular trauma, arteriovenous access for hemodialysis, and peripheral arterial disease. The production of the functional 3.5mm HAV is indicative of the potentially broad application of Humacyte's proprietary bioengineered tissue platform and manufacturing processes. Humacyte also presented preclinical data on the 3.5mm HAV in pediatric heart disease at the American Heart Association's Scientific Sessions 2021. The HAV is an investigational product candidate and is not currently approved for sale by the U.S. Food and Drug Administration or any international regulatory authority.

"We believe these results further underscore the promise of our bioengineered tissue platform beyond our 6mm clinical-stage vascular indications and moving towards cardiac surgical procedures," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "We were pleased to see the small-diameter HAV remained patent and to have observed vascular host-cell repopulation comparable to clinical data observed in multiple 6mm HAV clinical studies. We look forward to continuing to evaluate the small-diameter HAV in CABG and Blalock-Taussig-Thomas shunt, and to exploring the potential of our off-the-shelf regenerative medicine technology in a range of indications with critical unmet medical needs."

The presentation will be available on Humacyte.com.

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. 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 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. 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 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 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.

Humacyte Investor Contact:
investors@humacyte.com

Humacyte Media Contact:
media@humacyte.com