Humacyte Presents Preclinical Results of Small-Diameter HAV™ for Use as a BTT Shunt in Pediatric Heart Disease at American Heart Association's Scientific Sessions 2021

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-- Patency and host cell remodeling of the HAV were observed in all study implants –

-- Preclinical study is one component of Humacyte's expansion of the testing of the HAV in a broader cardiac bypass surgery application –

DURHAM, N.C., Nov. 16, 2021 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced positive results from a preclinical study of the small-diameter (3.5mm) HAV in a primate model simulating pediatric heart disease were presented at the American Heart Association's (AHA) Scientific Sessions 2021.

In this initial preclinical study, five non-immunosuppressed juvenile primates were surgically implanted with the 3.5mm diameter HAVs as modified Blalock-Taussig-Thomas shunts (mBTTs). The mBTT shunt operation is used as an initial stage of some pediatric surgical procedures to repair severe congenital heart defects. The 3.5mm HAVs were implanted into primates as mBTT shunts using standard surgical techniques, and the animals were studied for three to six months. Each of the HAVs remained patent during the study and exhibited repopulation with vascular cells. Two of the primates showed a stronger xenogeneic response to the human HAV material, an often expected outcome when implanting human tissue into animals, that resulted in mid-graft dilatations. The presentation was made at the AHA meeting by Humacyte Senior Preclinical Scientist Kevin Nash, Ph.D.

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. Preclinical testing of the 3.5mm HAV is also underway in adult primates, and these preclinical studies are designed to support the future advancement of the HAV into adult human studies in Coronary Artery Bypass Grafting (CABG).

"Exploring the potential use of the HAV in cardiac surgical procedures represents a logical expansion of Humacyte's bioengineered vascular platform. Our HAVs are being tested in high-fidelity primate models of human heart disease, progressing our off-the-shelf regenerative medicine technology beyond the three vascular indications currently being evaluated in clinical trials," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "We have observed that HAVs repopulate with the patient's own cells to become living vascular tissues. This data demonstrates the potential of the small diameter HAV to remodel and regenerate in a similar way to become a living cardiovascular tissue, expanding the possibilities of the HAV platform, and potentially providing small diameter HAVs in the future as off-the-shelf options to improve outcomes in cardiac bypass surgery."

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