Humacyte Publishes Preclinical Results Showing Human Acellular Vessel™ (HAV™) Patency as Modified Blalock–Taussig–Thomas Shunt in Juvenile Primate Model

-Outcomes exhibit potential of HAV for palliative treatment of congenital heart disease-

DURHAM, N.C., Oct. 16, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced publication of a preclinical study showing the potential for its investigational small-diameter Human Acellular Vessel™ (HAV™) to treat Tetralogy of Fallot, a heart condition that affects one in every 2,000 babies born each year.

The publication in the open-access *Journal of Thoracic and Cardiovascular Surgery (JTCVS Open)*, entitled "Evaluation of tissue-engineered human acellular vessels as a Blalock–Taussig–Thomas shunt in a juvenile primate model," describes a preclinical study in which researchers from Humacyte and Nationwide Children's Hospital (Columbus, OH) implanted 3.5mm diameter HAVs into a juvenile large-animal model of pediatric heart disease. The 3.5mm HAV was implanted between the subclavian and pulmonary arteries, to mimic a commonly-performed surgical procedure used to treat babies born with Tetralogy of Fallot, one of the most common pediatric heart conditions. The study assessed the HAV's patency, structure, and blood flow from one week to six months after the implant. The 3.5mm HAVs remained patent for up to six months, and evidence of HAV repopulation by host cells was observed, similar to what has been observed in human patients implanted with 6.0mm HAVs. This study also demonstrates the successful extension of Humacyte's manufacturing platform, from the production of 6.0mm vessels to 3.5mm vessels. Humacyte's 3.5mm HAV is also currently being tested in large-animal models of adult coronary artery bypass grafting (CABG) to assess the potential of the Humacyte platform to make vessels treating a range of heart conditions, spanning from pediatric to adult.

"In this preclinical study, the surgically implanted human acellular vessel remained patent for up to six months," said Christopher Breuer, M.D., director of the Center for Regenerative Medicine in the Abigail Wexner Research Institute at Nationwide Children's Hospital and senior author of the study. "The HAV was repopulated with host cells, and additional research will assess the growth capability of the grafts."

"Babies suffering from congenital heart disease face significant, often lifelong, medical challenges. In particular, many babies born with heart disease must undergo multiple re-operations as they grow, since the synthetic grafts used to repair their hearts do not grow with them. If the HAV can be shown to grow with the child, this could be transformational for the care of these babies born with heart disease," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "We are encouraged by the results of this new study and are optimistic that the HAV may eventually provide pediatric heart patients with another treatment option."

The 6.0mm HAV has accumulated more than 1,000 patient-years of experience worldwide in a series of clinical trials in multiple indications, including vascular trauma repair, arteriovenous access for hemodialysis, and peripheral artery disease. The 3.5mm HAV is being studied in preclinical models in several different potential indications.

The HAV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

About Humacyte

Humacyte, Inc. (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues, advanced tissue constructs, 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 HAVs, is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, AV 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 AV access in 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. Humacyte's 6mm HAV for urgent arterial repair following extremity vascular trauma also has received RMAT 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; the timing or likelihood of regulatory filings and approvals; timing, scope, and rate of reimbursement for our HAVs; the outcome of our ongoing discussions with the FDA concerning the design of our ongoing V005 Phase 2/3 clinical trial, including determination of trial size, and the scope of any approved indication 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, 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, 2022, 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. Except as required by law, we have no current intention of updating any of the forward-looking statements in this press release. 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:
Rich Luchette
Precision Strategies
+1-202-845-3924
rich@precisionstrategies.com
media@humacyte.com