



Humacyte Presents Six-Month Human Acellular Vessel™ (HAV™) Coronary Artery Bypass Graf (CABG) Data at the American Heart Association Scientific Sessions 2022 Meeting

November 7, 2022

Six-month primate HAV CABG model demonstrates patency, recellularization and remodeling resembling native blood vessels

HAV may address many limitations of current standard of care grafts used in CABG procedure

DURHAM, N.C., Nov. 07, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissues and advanced tissue constructs and organ systems at commercial scale, announced updated six-month results of the HAV in a baboon CABG model. These data were presented in two oral presentations at the annual American Heart Association (AHA) Scientific Sessions meeting, held in Chicago, Illinois from November 5-7, 2022.

Alan P. Kypson, M.D., FACS, thoracic surgeon at UNC Rex Hospital and lead investigator in Humacyte's large animal pre-clinical development of vessels for coronary artery bypass grafting, provided a six-month patency update of the HAV in a baboon CABG model in a presentation entitled "Six-Month Patency of Bioengineered Human Acellular Vessels in a Primate Model of Coronary Artery Bypass Grafting." The preclinical study assessed early patency at six months and the tolerability of a small-diameter (3.5mm) HAV as the vascular conduit used in a primate CABG model. The data presented consisted of three baboons, aged eight to 10 years, in which the HAV was implanted as an aorta-to-right coronary artery (RCA) graft. At six months, the HAV was explanted and studied with histological analysis. The HAVs were found to be repopulated with the subjects' own cells to resemble a native blood vessel and were patent, demonstrated by CT angiography. The HAV used as a vascular conduit in CABG procedures may address the long-term patency, availability and consistency issues associated with the current standard of care.

"Coronary artery bypass grafting is one of the most common surgical procedures in the U.S. However, the graft used in up to 90 percent of cases, the saphenous vein, has a 10 percent to 25 percent failure rate at one year and a 40 percent to 50 percent failure rate at 10 years," said Dr. Kypson. "Additionally, availability, complications in harvesting, and a wide variability in quality and size often plague the successful use of this current standard of care. We found that the HAVs were patent at six months and repopulated with the patients' own cells, potentially addressing many of the long-term concerns with current CABG graft standards of care."

Humacyte's Chief Executive Officer, Laura Niklason, M.D., Ph.D., also presented a platform overview of the HAV in a presentation entitled, "From Concept to Patient: Bringing Inventions Forward." The HAV pipeline holds multiple potential commercial opportunities, including the vascular tissue construct indications of trauma and arteriovenous access in hemodialysis in Phase 3, peripheral arterial disease in Phase 2, and pediatric heart disease and CABG in pre-clinical stages. In addition, the development of advanced organ systems, including the biovascular pancreas, continue to progress through preclinical stages. Dr. Niklason provided an update on the first potential commercial indication for the HAV, vascular trauma, and reported that in the ongoing single-arm, open-label, unblinded Phase 2/3 trial in vascular trauma the HAV performance-to-date compares favorably to both current standards of care, saphenous vein and expanded polytetrafluoroethylene (ePTFE) grafts, based on historical reported literature. In the Phase 2/3 trial to date the HAV has demonstrated low rates of amputation, low rates of infection (despite multiple implantations into contaminated wounds), and zero instances of HAV rejection.

Dr. Niklason additionally reviewed the ability for the HAV to potentially transform coronary artery bypass grafting with greater durability of surgical results and decreased morbidity of the procedure. Utilizing and harvesting a saphenous vein graft (SVG) to restore blood flow during a CABG procedure can be painful and can lead to persistent surgical site numbness, infection, swelling, and poor graft longevity requiring re-grafting procedures. The HAV is durable and uniform in diameter and quality, providing a constant that is not always available in saphenous vein grafting, with the potential to deliver surgeons with a consistent off-the-shelf vascular tissue conduit. The Humacyte CABG program is currently in non-human primate trials to evaluate the safety and potential benefits in order to support first-in-human clinical trials.

"Humacyte has successfully brought the HAV from concept to proof of concept to wholly-owned commercial-scale production," said Dr. Niklason. "Humacyte was the first company to receive the FDA Regenerative Medicine Advanced Therapy designation from the Food and Drug Administration. We also received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense. With our two Phase 3 HAV indications in progress, we are planning for a 2023 BLA submission in vascular trauma, followed by BLA submission in arteriovenous access for hemodialysis."

Presentation Details:

Presentation Title: [From Concept to Patient: Bringing Inventions Forward](#)

Session Title: Frontiers in Science: Vascular Devices - Bringing Novel Devices to Patients

Presenting Author: Laura Niklason, M.D., Ph.D., Humacyte CEO

Presentation Date/Time: Friday, November 4, 2022, 3:15 – 4:15 PM CT

Presentation Title: [Six-Month Patency of Bioengineered Human Acellular Vessels in a Primate Model of Coronary Artery Bypass Grafting](#)

Session Title: Preclinical Testing of Bioengineered Cell and Tissue Therapies for Cardiovascular Diseases

Presenting Author: Alan P. Kypson, M.D., Thoracic Surgeon, UNC Rex Hospital

Presentation Date/Time: Sunday, November 6, 2022, 8:00 – 9:00 AM CT

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 more than 500 patients. 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 benefits and risks related to our humanitarian efforts in the Ukraine; 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:

Elizabeth Miller, M.D.
LifeSci Communications LLC
+1-646-791-9705
emiller@lifescicomms.com