Humacyte Highlights First-in-Human Coronary Bypass Study at American Heart Association Scientific Sessions 2026

– Humacyte has initiated the CABG clinical study and looks forward to the commencement of screening for potential patients.

– "Moving it into a first-in-human study is the step that will tell us whether an off-the-shelf conduit can perform in the coronary position," says cardiothoracic surgeon Alan Kypson, M.D.

DURHAM, N.C., Nov. 09, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, announced that it has initiated the Phase 2a study of its investigational coronary tissue engineered vessel (CTEV) in patients undergoing coronary artery bypass grafting (CABG). The CTEV and the Company's regenerative medicine platform were highlighted in three presentations at the American Heart Association (AHA) Scientific Sessions 2026 in Chicago, Illinois. The AHA Scientific Sessions is one of the world's largest gatherings of cardiovascular clinicians and scientists.

On Saturday, November 7, John H. Alexander, M.D., M.H.S., Professor of Medicine/Cardiology, Duke Clinical Research Institute at Duke University and Alan Kypson, M.D., Cardiothoracic Surgeon at UNC Rex Hospital, presented the design of the Phase 2a study in "First-in-Human Phase 2a Study Design of a Bioengineered Human Coronary Artery for Coronary Artery Bypass Grafting." The FDA accepted Humacyte's Investigational New Drug (IND) application in July 2026, and the study will evaluate the safety and efficacy of the CTEV as a vascular conduit in ten adult patients with coronary artery disease. Patency will be assessed two months after implant, and patients will be followed for up to three years. The study is now open for enrollment.

"Every cardiac surgeon has faced the patient who needs a bypass, but doesn't have usable vein, and our options in those cases are limited," said Dr. Kypson. "I have worked with this vessel in large-animal models for years and moving it into a first-in-human study is the step that will tell us whether an off-the-shelf conduit can perform in the coronary position."

More than 400,000 coronary arterial grafts are placed each year in the United States. The current conduits used for CABG are autologous vessels harvested from the patient, most often the saphenous vein in the leg. However, saphenous vein graft patency at one year is often as low as 75%, and harvesting the vein can cause surgical wound complications such as infection, and some patients do not have adequate vein available. The CTEV is a small-diameter bioengineered vessel designed as an off-the-shelf conduit for CABG and is produced using the same manufacturing system as Humacyte's FDA-approved acellular tissue engineered vessel (ATEV).

On Saturday, November 7, Dr. Niklason delivered an invited talk, "Engineering the Microenvironment to Accelerate Vascular Regeneration," in a special session on bioengineering human tissue for congenital heart disease, describing how Humacyte's acellular engineered vessels are designed to be repopulated by a patient's own cells after implantation, and may serve as materials to form biological heart valves that could grow with the pediatric patient.

"The Phase 2a CABG study marks the first time our bioengineered vessel technology will be evaluated in coronary bypass surgery, and it builds on years of preclinical work in multiple large-animal models," said Dr. Niklason. "Our goal with the CTEV is to give cardiac surgeons an off-the-shelf conduit that can repopulate with a patient's own cells, without the need to harvest a vein from the leg or an artery from the arm."

On Sunday, November 8, Robert Kirkton, Ph.D., Executive Director of New Product and Process Development at Humacyte, presented results from porcine and ovine CABG models in "Evaluation of Tissue Engineered Human Vessels in Porcine and Ovine Models of Coronary Artery Bypass Grafting." These results included successful implantation of ~12 cm-long CTEV bypasses for up to three months in sheep demonstrating patency and host recellularization of the CTEV wall with smooth muscle cells as well as luminal endothelial cells along the length of the CTEV CABG conduit. This work builds on a previous preclinical CABG study in baboons, published in *JACC: Basic to Translational Science*, in which the CTEV maintained mechanical integrity and conduit patency for up to six months while becoming recellularized with host vascular smooth muscle and endothelial cells.

The CTEV 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 Biologics License Application for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication was approved by the FDA in December 2024. ATEVs are also currently in late-stage clinical trials targeting other vascular applications, including arteriovenous (AV) access for hemodialysis and peripheral artery disease (PAD). 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 ATEV 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 ATEV for urgent arterial repair following extremity vascular trauma and for advanced PAD also have received RMAT designations. The ATEV received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense. For more information, visit www.Humacyte.com.

For uses other than the FDA approval in the extremity vascular trauma indication, the ATEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

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, our plans and ability to commercialize Symvess and, if approved by regulatory authorities, our product candidates, successfully and on our anticipated timelines; the degree of market acceptance of and the availability of third-party coverage and reimbursement for Symvess and, if approved by regulatory authorities, our product candidates; our ability to manufacture Symvess and, if approved by regulatory authorities, our product candidates in sufficient quantities to satisfy our clinical trial and commercial needs; the anticipated benefits of our ATEVs relative to existing alternatives; our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding our ongoing or planned clinical trials; the anticipated characteristics and performance of our ATEVs; the implementation of our business model and strategic plans for our business; our ability to execute and achieve the expected benefits of our cost-saving measures and whether our efforts will result in further actions or additional asset impairment charges that adversely affect our business; and the timing or likelihood of regulatory filings, acceptances and approvals. 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, competitive and/or reputational factors, and other risks and uncertainties, including those described under the header “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2024 and Form 10-Q for the quarter ended March 31, 2025, each 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.

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