Humacyte Announces Publication of Preclinical Data on Use of the CTEV as a Coronary Artery Bypass Graft (CABG)

- Results were published in JACC: Basic to Translational Science -

- Publication evaluated coronary tissue engineered vessel (CTEV) as a conduit for CABG in a nonhuman primate model -

- All implanted CTEVs remained patent through six months, demonstrated adaptive remodeling, and recellularized with host coronary artery cells –

- Humacyte plans to advance CTEV into first-in-human study in CABG -

DURHAM, N.C., Sept. 18, 2025 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced the publication of new preclinical data as part of a study evaluating the coronary tissue engineered vessel (CTEV) as a coronary artery bypass graft conduit in a non-human primate model. In the study, published in *JACC: Basic to Translational Science,* a specialist journal launched by the *Journal of the American College of Cardiology (JACC),* the CTEV was observed to sustain blood flow, recellularize with the animals' host cells, and remodel to reduce the initial size mismatch between the CTEV and the animals' native artery.

"Innovation in CABG has been stagnant for far too long," said Alan Kypson, MD, FACS, Cardiothoracic Surgeon, UNC REX Hospital. "Our results suggest that we may be on the verge of a new option — one that remodels to match the native artery and recellularizes with host cells, potentially providing superior patency relative to saphenous vein grafts. The CTEV has the potential to address a significant unmet clinical need in coronary bypass surgery and ultimately improve patient outcomes."

Cardiovascular disease is the leading cause of death worldwide, comprising one in every three deaths in the United States in 2023. The most common form is coronary artery disease (CAD), which affects 1 in 20 adults aged 20 and older. Coronary artery bypass grafting, a procedure that improves blood flow to the heart by using the internal mammary artery and saphenous vein to bypass narrowed or blocked coronary arteries, remains the current standard of care. However, saphenous vein grafts - used in 80%-90% of CABG cases - demonstrate poor long-term patency, with approximately 50% failing at 10 years. Many patients also lack usable autologous veins or arteries due to prior harvest, ablation, or poor quality, highlighting the unmet clinical need for alternative conduits. For the past half century, no novel CABG conduits have gained routine clinical use.

The recent JACC study, titled *"Acellular Tissue Engineered Vessels as Coronary Artery Bypass Grafts",* follows five adult baboons undergoing CABG to the right coronary artery with the CTEV. All CTEVs remained patent throughout the 6-month study. At the end of follow-up, the CTEV was observed to have recellularized with host cells to form a multi-layered tissue, including transanastomotic neomedial tissue that effectively reduced the initial size mismatch with the right coronary artery (RCA). The results suggest that the CTEV may be a durable alternative CABG conduit. The CTEV is 3.5mm blood vessel produced in the same bioengineering manufacturing system as Humacyte's acellular tissue engineered vessel (ATEV™). The CTEV is also referred to as the small-diameter ATEV, or sdATEV.

Humacyte also announced that it plans to advance the CTEV into its first-in-human study in CABG. To support human study, the Company anticipates filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) during the 4th Quarter of 2025. The Company's current plans for filing an IND are based on the outcome of a meeting held early this year with the FDA, including agreements reached with the agency.

"We're pleased that this new publication of preclinical data demonstrates the promise of CTEVs as an alternative for native vessel grafts in CABG," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "As one of the leading causes of early death, coronary artery disease poses unique challenges for patient care. We are looking forward to proceeding into the first-in-human study of the CTEV in CABG and hopefully offering surgeons another option for treating this disease."

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 extremity vascular trauma 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 and our CTEVs 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 and our CTEVs; 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 June 30, 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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