# Humacyte Announces FDA Acceptance of IND for First-In-Human Clinical Study of CTEV for Coronary Artery Bypass Grafting

*– Phase 2a study of CTEV in coronary artery bypass grafting (CABG) is expected to start this quarter –*

*– Progression of CTEV into human study supported by positive preclinical results presented at multiple scientific meetings and in a recent publication –*

DURHAM, N.C., July 27, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced that the Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for a first-in-human clinical study of the coronary tissue engineered vessel (CTEV) in coronary artery bypass grafting (CABG). Humacyte plans to initiate a Phase 2a study of the CTEV in CABG patients during the current quarter.

“No new off-the-shelf conduits have been introduced for CABG in the past 40 years, and our IND clearance and upcoming Phase 2a study are major milestones for the CTEV as a potential innovation in CABG,” said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. “Our preclinical results suggest that the CTEV may be a promising off-the-shelf alternative to saphenous vein grafts in CABG, and we look forward to evaluating this prospect in its first human clinical study.”

The FDA has approved Humacyte’s study design for a first-in-human clinical trial titled “A Phase 2a Study for the Evaluation of Safety and Efficacy of Humacyte's Coronary Tissue Engineered Vessel (CTEV) as a Vascular Conduit for Coronary Artery Bypass Grafting in Patients with Coronary Artery Disease,” to be conducted in ten adult patients. An assessment of patency (blood flow) through the CTEV will be performed two months after implant, and patients will be followed for up to three years.

There are over 400,000 coronary arterial grafts placed each year in the United States, and the surgery has been shown to improve the survival and quality of life for many patients with coronary artery disease. The current conduits used for CABG are autologous vessels, including the internal mammary artery, the radial artery and saphenous vein, which is used in the majority of CABG operations. However, saphenous vein graft (SVG) patency at one year is often as low as 75%, and SVG harvesting from the patient can result in variable vein quality as well as surgical wound complications, such as infection, that can prolong hospitalization and require additional surgical interventions. In addition, a number of patients do not have adequate saphenous vein available for use in surgical bypass.

The CTEV is a first-in-class, universally implantable bioengineered human blood vessel produced in the same manufacturing system as Humacyte’s FDA-approved acellular tissue engineered vessel (ATEV). CTEV is designed to be available off-the-shelf, and does not require further injuring the patient to obtain arterial replacement material. In preparation for the planned Phase 2a study, the CTEV has been studied in preclinical CABG models in pigs, sheep and baboons. The results of a six-month preclinical study in baboons were recently published in *JACC: Basic to Translational Science* and the CTEV was observed to sustain patency, recellularize with host vascular smooth muscle and endothelial cells, and remodel to effectively reduce the initial size mismatch between the CTEV and the animals’ right coronary arteries.

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

**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..

**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 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 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, 2025 and the form 10-Q for the quarter ended March 31, 2026, each as 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