Humacyte Announces Planned IND Filing in 2025 to Support First-In-Human Clinical Study of Small-Diameter ATEV™ for Coronary Artery Bypass Grafting

– Plans for filing an IND was agreed with the FDA in a recent meeting –

– Positive preclinical results of the small-diameter ATEV were recently presented at The American Heart Association's Scientific Sessions 2024 meeting –

DURHAM, N.C., Jan. 21, 2025 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced that it plans to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to allow first-in-human clinical testing of the small-diameter (3.5mm) acellular tissue engineered vessel (sdATEV) in coronary artery bypass grafting (CABG). The Company's current plans for filing an IND are based on the outcome of a recent meeting held with the FDA, including agreements reached with the agency. To date only the 6.0mm configuration of the ATEV has been studied in human trials, specifically in studies conducted in vascular trauma repair, arteriovenous (AV) access for hemodialysis, and peripheral artery disease (PAD).

To enable the IND filing, the sdATEV has been studied in multiple preclinical CABG models. The results of a six-month preclinical study in primates were presented in November 2024 at The American Heart Association's *Scientific Sessions 2024* meeting. In the preclinical CABG model, the sdATEV was observed to sustain patency (blood flow), recellularized with the animals' host cells, and remodeled to effectively reduce the initial size mismatch between the sdATEV and the animals' native artery.

"We are very pleased to be moving closer to human clinical studies of the sdATEV in CABG, and our planned IND filing and initiation of first-in-human study after the FDA clearance will be a major milestone for Humacyte," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "Our preclinical results suggest that the sdATEV may be a promising off-the-shelf alternative to native vessel grafts in CABG, and we look forward to evaluating this possibility in human clinical studies."

There are over 400,000 CABG procedures 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 left internal mammary artery and saphenous vein, which is used in 80-90% of CABG surgeries. However, saphenous vein graft (SVG) patency at one year is often as low as 75% and SVG harvest can result in surgical wound infection potentially leading to prolonged hospital stay, need for revascularization, and limb-loss. In addition, some patients do not have usable saphenous vein available for surgical bypass.

"Coronary artery bypass graft (CABG) surgery can be lifesaving in appropriately selected patients with coronary artery disease," said John H. Alexander, MD, MHS, Professor of Medicine, Department of Medicine, Division of Cardiology, Senior Investigator at the Duke Clinical Research Institute at Duke University. "A long-standing, major limitation of CABG surgery has been the availability of ideal conduits to use as bypass grafts. If clinical trials are successful, this tissue-engineered graft could have the potential to transform CABG surgery by providing an unlimited supply of an off-the-shelf conduit to use in patients undergoing CABG surgery. We look forward to helping to advance this technology into human studies."

The ATEV is a first-in-class bioengineered human tissue that is designed to be a universally implantable vascular conduit for use in arterial replacement and repair. Harvesting vein from a CABG patient may lead to complications and may not be feasible due to missing or diseased veins, ATEV is designed to be available off-the-shelf, and does not require further injuring the patient to obtain arterial replacement material.

The FDA granted a full approval for the ATEV (Symvess™) on December 19, 2024 for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein graft is not feasible. For uses other than the FDA approval, 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. 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, the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our ATEV; our ability to successfully

complete preclinical and clinical trials for our ATEVs; the anticipated benefits of the our ATEVs relative to existing alternatives; the expected success of our sales team; the validity of our Budget Impact Model; the anticipated commercialization of our ATEVs and our ability to manufacture at commercial scale; the implementation of our business model and strategic plans for 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, and/or competitive 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, 2023, filed by Humacyte with the SEC, and in subsequent 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

Source: Humacyte, Inc