Humacyte Presents Preclinical Results of Small-Diameter ATEV™ for Coronary Artery Bypass Grafting at American Heart Association's Scientific Sessions 2024

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DURHAM, N.C., Nov. 18, 2024 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, announced the presentation of positive preclinical results of the small-diameter (3.5mm) acellular tissue engineered vessel (sdATEV) in a non-human primate model of coronary artery bypass grafting (CABG). In the six-month 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.

The preclinical results were presented in a poster titled "Acellular Tissue Engineered Vessels as Conduits for Coronary Artery Bypass Grafting" at The American Heart Association's (AHA) *Scientific Sessions 2024* meeting on Saturday, November 16, 2024, in Chicago, IL by two of the study researchers, Rob Kirkton, PhD, Humacyte Director of New Product Development and Alan Kypson, MD, FACS, FACC, Cardiothoracic Surgeon, UNC REX Hospital.

In the preclinical study, the sdATEV was implanted between the aorta and right coronary artery (RCA) in five baboons to simulate a CABG procedure. Animals were followed for six months after sdATEV implantation and all sdATEVs maintained patency throughout the study. The baboon study provided an effective model for demonstrating the feasibility, mechanical durability and capacity for host-cell remodeling of the sdATEV for CABG. After implantation, the sdATEV was observed to recellularize with host cells and remodel to form a multi-layered tissue including transanastomotic neomedial tissue that effectively reduced the initial size mismatch with the RCA. The neomedial tissue observed at six months was predominantly composed of quiescent contractile smooth muscle cells under a lining of functional endothelial cells.

"Our results show that the sdATEV not only supports coronary blood flow but also host recellularization and adaptive remodeling in a challenging preclinical surgical model," said Dr. Kirkton.

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, a number of patients do not have usable saphenous vein available for surgical bypass.

"This study suggests that the sdATEV may be a promising off-the-shelf alternative to saphenous vein grafts in CABG, which is a major unmet clinical need," said Dr. Kypson.

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. Humacyte develops and manufactures acellular tissues to treat a wide range of diseases, injuries, and chronic conditions. Humacyte's initial product candidates, a portfolio of ATEVs, are currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous (AV) access for hemodialysis, and peripheral artery disease. A Biologics License Application for the ATEV in the vascular trauma indication is currently under review by the FDA and was granted Priority Review. 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 an 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 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.

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