Humacyte Acellular Tissue Engineered Vessel (ATEV™) Receives FDA's Regenerative Medicine Advanced Therapy (RMAT) Designation for Patients with Advanced Peripheral Artery Disease (PAD)

– Third RMAT designation by FDA for ATEV –

– RMAT will expedite development of ATEV in PAD –

DURHAM, N.C., July 01, 2024 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, has been granted the U.S. Food and Drug Administration's (FDA's) Regenerative Medicine Advanced Therapy (RMAT) designation for patients with advanced peripheral artery disease (PAD). This RMAT designation is granted at the same time as FDA cleared a new Investigational New Drug (IND) application for the PAD indication for Humacyte's investigational Acellular Tissue Engineered Vessel (ATEV), formerly referred to as the "HAV". The RMAT designation is designed to provide pathways for expedited development and review of regenerative medicine therapies for serious or life-threatening diseases or conditions. The designation allows for close interactions with the FDA and potentially an expedited/priority review of a Biologics License Application (BLA). This is the third RMAT designation granted by the FDA for Humacyte's ATEV, in addition to previous RMAT designations for vascular trauma repair and arteriovenous (AV) access in hemodialysis.

"We are very pleased to receive our third RMAT designation from the Food and Drug Administration," said Dr. Cindy Cao, Chief Regulatory Officer at Humacyte. "The RMAT designation we previously received in our lead indication of vascular trauma was very helpful in enhancing our communication with the FDA review team during the filing and review of our BLA. We are excited that this additional designation has been granted in advanced PAD, as we expect that it will further strengthen our communication with the FDA and expedite the development of our ATEV in this important indication."

Humacyte's ATEV is designed to be a universally implantable vascular conduit for use in vascular replacement and repair. Importantly, the ATEV has been observed to have a low rate of infection in clinical trials and is designed to be available off-the-shelf and ready whenever surgeons need it, potentially saving valuable time and improving patient outcomes. PAD is a cardiovascular disease of blood vessels, affecting the arteries in the legs most commonly. As many as 40% of patients requiring a bypass to the arteries of the lower leg do not have autologous vein available for revascularization, which is the standard of care for such patients. The ATEV has been evaluated in two Phase 2 studies in PAD, with patients followed for as long as six years. In addition, The Mayo Clinic, Rochester, MN, is conducting a study in approximately 30 patients with chronic limb-threatening ischemia, the end stage of PAD, under an investigator IND cleared by the FDA. All patients treated with the ATEV for PAD to date have not had autologous vein available for revascularization, and hence the ATEV may represent an important therapeutic alternative for such patients.

The ATEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency. As announced previously, based on guidance from the FDA, the common (non-brand) name "Acellular Tissue Engineered Vessel" (ATEV) replaces the term 'Human Acellular Vessel" (HAV) previously used for the engineered vessel product candidate.

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 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 is currently under review by the FDA and was granted Priority Review with a PDUFA date of August 10, 2024. 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 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 expected PDUFA date for our ATEV in vascular trauma repair; the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials, including our BVP program; the anticipated characteristics and performance of our ATEVs and the BVP; our ability to successfully complete, preclinical and clinical trials for our ATEVs and the BVP; the anticipated benefits of the BVP 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 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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