



Humacyte Announces Issuance of U.S. Patent Covering Manufacturing of Symvess™ and Other Bioengineered Tissues

– Patent provides coverage into 2040 for key aspects of the bioreactor manufacturing system –

– Symvess, the acellular tissue engineered vessel, is manufactured in this patented system –

DURHAM, N.C., Feb. 27, 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 issuance of a U.S. Patent covering key aspects of the manufacturing of Symvess (acellular tissue engineered vessel-tyod) and other bioengineered human tissues. U.S. Patent No. 12,195,711, titled "Drawer System for Cultivating Tissue," covers key aspects of the bioreactor system that Humacyte uses to manufacture bioengineered human tissues. The newly issued patent provides protection into 2040. The new patent complements a family of existing patents and patent applications encompassing the design and composition of Humacyte's products, and their methods of manufacture.

Humacyte's lead product Symvess, or the ATEV™ (acellular tissue engineered vessel-tyod), 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. The ATEV is produced in proprietary manufacturing systems, including the LUNA200™ production equipment, that are covered by the newly issued U.S. patent. The Company has an 83,000 square foot bioprocessing facility, with the ability to manufacture human tissue of different diameters and lengths at commercial scale.

The U.S. Food and Drug Administration (FDA) granted a full approval for 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. In contrast to harvesting a vein from the patient in the setting of acute trauma, which causes further injury and takes valuable time, Symvess is available off-the-shelf, and does not require further injuring the patient. The ATEV is also being evaluated in clinical trials in arteriovenous (AV) access for hemodialysis and peripheral artery disease, and preclinical development is underway in coronary artery bypass grafts.

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 initial product candidates, a portfolio of acellular tissue engineered vessels (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 was approved by the FDA in December 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 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, our plans and ability to commercialize our ATEV in the United States under the brand name SYMVESS in vascular trauma repair; the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our ATEVs; our ability to successfully complete preclinical and clinical trials for our ATEVs; the anticipated benefits of the ATEV 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, our quarterly report on Form 10-Q for the quarter ended September 30, 2024, 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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