Humacyte Announces Publication of the Budget Impact Model (BIM) for Symvess™ (acellular tissue engineered vessel-tyod) in the Journal of Medical Economics

– Symvess is a first-in-class bioengineered human tissue designed to be a universally implantable vascular conduit for use in arterial replacement and repair –

– Publication of the Budget Impact Model in peer-reviewed journal supports Symvess as a treatment that provides economic value to hospitals and payers –

DURHAM, N.C., March 10, 2025 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced the publication of the Budget Impact Model for Symvess in the *Journal of Medical Economics*. The publication, titled "Budget impact model of acellular tissue engineered vessel for the repair of extremity arterial trauma when autologous vein is not feasible," reported that Symvess was projected to be cost saving for both trauma centers and third-party payers, primarily due to reductions in the costs related to amputations and conduit infections.

"Demonstrating economic value to the health care system is the next major step in the successful commercialization of Symvess and complements the recent publication of efficacy and safety result in *JAMA Surgery*," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "The economic modeling described in this peer-reviewed publication confirms that the avoidance of vascular infections and amputations to be strong opportunities for cost reduction with the use of Symvess in this patient population. Economic models are employed by health care decision-makers to more fully understand the financial implications of a product given its expected clinical performance and its potential impact on short- and long-term patient outcomes. The Symvess Budget Impact Model has already been used by Value Analysis Committees to review and approve Symvess for use by their surgeons."

This publication used inputs from the PROOVIT vascular trauma registry, databases of hospital charges and insurance claims, published literature, and expert opinion to evaluate the economic impact from the perspective of Level I trauma centers and third-party commercial, Medicare and Medicaid payers. The publication was developed in collaboration with health economists and vascular surgeons to ensure that current practices in extremity arterial trauma practices were reflected, and that current health economic modeling standards were followed. Based on the model, the per-patient cost for trauma centers of treating patients with Symvess is estimated to be less than the cost of treating trauma patients with synthetic and other non-autologous grafts. Average per-patient costs for trauma centers were estimated to be $154,722 for cryopreserved allograft, $140,428 for bovine xenograft, $137,213 for prosthetic graft and $121,615 for Symvess (this includes the $29,500 purchase price for Symvess). The major drivers of cost savings associated with Symvess across all stakeholders were attributed to reductions in the rate of vascular conduit infection and amputation. The model also showed greater savings for third-party payers (compared to trauma centers) due to the avoidance of late complications occurring after patients' release from the hospital. For commercial payers, per-patient costs were estimated to be $181,127 for prosthetic graft, $179,850 for cryopreserved allograft and bovine xenograft, and $94,165 for Symvess.

The U.S. Food and Drug Administration (FDA) granted 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. Symvess, or the ATEV™ (acellular tissue engineered vessel), 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. While harvesting vein from a trauma patient takes valuable surgical time and is not always feasible due to damage to veins or to the limbs, Symvess is available off-the-shelf, and does not require further injuring the patient to obtain a vascular conduit. Humacyte's BLA included positive results from the V005 pivotal Phase 2/3 clinical study, as well as real-world evidence from the treatment of wartime injuries in Ukraine under a humanitarian aid program. Symvess was used to repair many types of traumatic injuries including car accidents, gunshot wounds, blast wounds, and industrial accidents. It was utilized by vascular and trauma surgeons in Level 1 Trauma centers throughout the U.S. and Israel to repair severe limb-threatening and life-threatening injuries, and in front-line hospitals in Ukraine to treat wartime injuries. Results from these studies were published in *JAMA Surgery* on November 20, 2024. In the civilian and military clinical studies, Symvess was observed to have high rates of patency, or blood flow, and low rates of amputation and infection.

INDICATION

SYMVESS is an acellular tissue engineered vessel indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: GRAFT FAILURE

Loss of SYMVESS integrity due to mid-graft rupture or anastomotic failure can result in life threatening hemorrhage.

CONTRAINDICATIONS

DO NOT use SYMVESS in patients who have a medical condition that would preclude long-term antiplatelet therapy (such as aspirin or clopidogrel) after resolution of acute injuries.

WARNINGS AND PRECAUTIONS

- **Graft Rupture**

Vascular graft rupture has occurred in patients treated with SYMVESS. Advise patients that arterial bleeding can be life-threatening and to seek emergent medical evaluation for any signs or symptoms of graft rupture such as bleeding, pain and swelling in the extremity, or signs of extremity

ischemia.

- **Anastomotic Failure**

Anastomotic failure has occurred in patients treated with SYMVESS. In clinical studies of SYMVESS, anastomotic failure occurred within the first 36 days post-implantation. Monitor patients for signs of anastomotic failure such as pain and swelling at the surgical site, decreasing hemoglobin or other signs and symptoms of bleeding. Advise patients to seek urgent medical evaluation if they have any signs or symptoms that may be indicative of anastomotic failure such as bleeding, swelling or worsening pain at the surgical site or changes in color of overlying skin.

- **Thrombosis**

Thrombosis has occurred in patients treated with SYMVESS. In clinical trials of SYMVESS, patients received antiplatelet therapy following implantation of SYMVESS to reduce the risk of thrombosis. The risk of thrombosis may increase in patients who discontinue antiplatelet therapy. Anti-platelet therapy is recommended following treatment with SYMVESS.

- **Transmission of Infectious Diseases**

SYMVESS is manufactured using cells and reagents that may transmit infectious diseases or infectious agents. The cells used in the manufacture of SYMVESS are derived from a donor who met the donor eligibility requirements for transmissible infectious diseases which includes screening and testing of risks associated with human immunodeficiency virus 1 (HIV-1), human immunodeficiency virus 2 (HIV-2), hepatitis B virus (HBV), hepatitis C virus (HCV), and syphilis (Treponema pallidum). The cell banks are tested negative for human and animal viruses, retroviruses, bacteria, fungi, yeast, and mycoplasma. While all animal-derived reagents are tested for animal viruses, bacteria, fungi, and mycoplasma before use, these measures do not eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents. Fetal bovine serum is sourced to minimize the risk of transmitting a prion protein that causes bovine spongiform encephalopathy and the cause of a rare fatal condition in humans called variant Creutzfeldt-Jakob disease. No transmissible agent infections have been reported during clinical testing.

ADVERSE REACTIONS

The most common adverse reactions (occurring at ≥ 10%), were vascular graft thrombosis, pyrexia (fever) and pain.

Please see full Prescribing Information at www.symvess.com, including Boxed Warning, for SYMVESS.

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. 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 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.

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.

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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