Humacyte Announces Commercial Launch of Symvess™ (acellular tissue engineered vessel-tyod) for Extremity Vascular Trauma

– The FDA has authorized Humacyte to release commercial shipments –

– Positive responses from surgeons and trauma centers to initial sales and marketing outreach –

- 21 hospitals have already initiated the Value Analysis Committee (VAC) approval process –

DURHAM, N.C., Feb. 26, 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 commercial launch of Symvess (acellular tissue engineered vessel-tyod) 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. The U.S. Food and Drug Administration (FDA) granted a full approval for Symvess on December 19, 2024. The FDA has now completed its required review of commercial batch information and has authorized Humacyte to commence commercial shipments.

Shortly after FDA approval, Humacyte began receiving requests for quotations for Symvess from hospitals. Twenty-one hospitals have already initiated the VAC approval process, with additional hospitals expected to commence the process. These hospitals are a mix of leading trauma centers that were participants in Humacyte clinical studies combined with institutions newly introduced to Symvess. Additionally, the hospitals span the range of individual institutions to centers providing access to larger hospital networks. Although the VAC process often takes three to six months to complete, two hospitals have already completed their review and approved the purchase of Symvess in advance of market launch. Humacyte has also been notified that a number of hospitals will purchase Symvess while the VAC process remains underway.

“This is a great moment for Humacyte but, more importantly, for patients in urgent need of arterial repair options to help save their limbs or lives.” said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. “After more than 20 years of research and development, we are thrilled to be able to deliver Symvess to hospitals and surgeons who are committed to improving patient outcomes. This commercial launch signifies a new era in vascular surgery and patient care and is the next growth phase for Humacyte. Our commercial team will continue to work closely with health care providers to ensure that Symvess is available to patients nationwide.”

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. In clinical studies, Symvess has been 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. In contrast to harvesting a vein from the patient, which causes further injury and takes valuable time, Symvess is available off-the-shelf, and does not require further injuring the patient. 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 has been used to treat many types of injuries arising from car accidents, gunshot wounds, blast wounds, and industrial accidents. Results from these civilian and wartime trauma studies were published in *JAMA Surgery* on November 20, 2024. In the clinical studies, Symvess was observed to have high rates of patency, or blood flow, and resulted in low rates of limb amputation and infection.

To communicate the health economic value of Symvess, Humacyte has developed a Budget Impact Model (BIM) based on the clinical results supporting the BLA, and the estimated reduction in clinical complications potentially achievable with the use of Symvess versus the current standard of care. Based on the BIM, the overall per-patient cost of treating patients with Symvess is estimated to be less than the cost of treating trauma patients with synthetic grafts, cryopreserved allografts, or xenografts. The major drivers of cost savings associated with Symvess stemmed from reductions in the rates of amputation and vascular conduit infection. A paper describing the BIM has already been accepted for publication in a major medical journal.

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. 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.

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.

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