Humacyte Provides Update on Commercial Launch and Pricing of Symvess™ (acellular tissue engineered vessel-tyod) for Extremity Vascular Trauma

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

– Highly experienced sales team onboard and trained in preparation for commercial launch –

– Budget Impact Model supports pricing of Symvess –

DURHAM, N.C., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced an update of plans for the commercial launch of Symvess (acellular tissue engineered vessel-tyod) for extremity arterial injury. Humacyte is responding to requests for quotations from hospitals and has initiated the Value Analysis Committee approval processes at multiple hospitals as part of the preparation for market launch.

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. Shortly after approval, Humacyte provided the final packaging and product batch release information required for FDA review prior to shipment of product. Humacyte currently expects to have authorization to commence product shipment early this quarter and continues to build product supply to support market launch.

Humacyte has recruited and trained a highly experienced sales team for the commercial launch of Symvess. All ten sales team members are multi-year President's Club winners, representing the top 10% of achievers in their prior sales organizations. All sales team members have demonstrated consistent overachievement with average hospital medical device and biotech experience exceeding 15 years. Each sales team member has experience in vascular surgery and/or trauma surgery, and 80% have previous experience selling regenerative therapies. All team members have experience selling clinically differentiated disruptive technologies and premium priced portfolios.

Humacyte announced that the price of Symvess will be $29,500 per unit. The Company has developed a Budget Impact Model based on the clinical results supporting the approval of Symvess, and the estimated reduction in clinical complications potentially achievable by treating specific patients with Symvess versus current standard of care. Based on the model, the 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. Major drivers of cost savings associated with Symvess were attributed to reductions in the rate of amputation and vascular conduit infection.

Additionally, Humacyte submitted an NTAP (New Technology Add-On Payment) application for Symvess to CMS in October 2024. Humacyte presented the Symvess data at a public Town Hall with the Centers for Medicare and Medicaid Services (CMS) on December 11, 2024. If successful, NTAP reimbursement will start for discharges on October 1, 2025, offering hospitals additional payment to cover a portion of the costs associated with Symvess.

"We are very excited to take the major steps in providing healthcare providers a novel alternative for treating patients suffering from extremity arterial injury," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "We are pleased to see interest from multiple hospitals and to have commenced the Value Analysis Committee approval processes. We look forward to the anticipated publication of our Budget Impact Model which highlights the major drivers of cost savings associated with Symvess and complement our strong clinical results."

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 vascular repair material. 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.

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