Humacyte Announces Publication of New Data Comparing Symvess™ to Autologous Vein in Extremity Arterial Trauma

- Results published in AAST's Trauma Surgery & Acute Care Open Journal -

- Study compared outcomes of patients treated with Symvess with patients in PROOVIT registry who were treated with vein -

- In a comparison to prior results in the PROOVIT registry, outcomes for Symvess and autologous vein were similar for treatment of vascular trauma -

DURHAM, N.C., Oct. 30, 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 publication of a new study comparing clinical outcomes of Symvess to autologous vein in the treatment of extremity arterial trauma. The study was published in the American Association for the Surgery of Trauma (AAST)'s *Trauma Surgery & Acute Care Open Journal*. The publication was entitled "Short-term Performance of Symvess™ Compared to External Control Data for Autologous Vein in Treatment of Extremity Arterial Trauma." Compared to pre-existing patients in a trauma registry who were treated with autologous vein, patients treated with Symvess experienced similar short-term outcomes for patency, limb salvage, and infection.

"Autologous vein has long been the gold standard for the treatment of extremity arterial trauma, and for good reason — it resists infection and maintains patency," said Luigi Pascarella, MD, Division Chief of Vascular Surgery, UNC School of Medicine, and one of the authors of the publication. "The fact that Symvess achieved similar short-term outcomes in this analysis demonstrates its potential as a reliable, off-the-shelf alternative when use of autologous vein is not feasible."

The comparative analysis leveraged data from two clinical trials — Humacyte's Phase 2/3 V005 study and the Humanitarian V017 study in Ukraine — and matched patients in those trials to patients from the Prospective Observational Vascular Injury Treatment (PROOVIT) registry, which is the world's largest vascular trauma database. The study found patients treated with Symvess had statistically similar clinical outcomes to those for patients from the PROOVIT registry who received autologous vein. Primary patency for Symvess versus the autologous vein group was 86.6% vs. 91.8%; secondary patency was 91.0% vs. 97.7%; amputation was 7.5% vs. 8.2%; conduit infection was 1.5% vs. 0%; and death was 4.5% vs. 4.5%, respectively.

The use of autologous vein to repair or replace a damaged blood vessel is the current standard of care for treating extremity arterial trauma because it offers excellent long-term patency and low infection rates. However, in many cases, suitable autologous vein may not be available due to extreme limb damage, prior surgeries, or poor vein quality. Even when available, harvesting the vein is a time-consuming procedure, and therefore not an option for many patients with severe traumatic injuries. Symvess (acellular tissue engineered vessel, or ATEV™) is designed to be immediately available off-the-shelf — saving critical surgical time in traumatic situations.

"Trauma and vascular surgeons treat some of the most complex and urgent cases imaginable — from gunshot injuries to wounds from blasts or ammunition on the battlefield," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "However, innovation in recent years has failed to provide them with good alternatives to autologous vein grafts for instances when treatments with these grafts is not feasible. The results of this study underscore Symvess' potential as a much needed safe, effective, and lifesaving alternative for treatment."

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 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 (PAD). 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 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 Symvess and, if approved by regulatory authorities, our product candidates, successfully and on our anticipated timelines; the degree of market acceptance of and the availability of third-party coverage and reimbursement for Symvess and, if approved by regulatory authorities, our product candidates; our ability to manufacture Symvess and, if approved by regulatory authorities, our product candidates in sufficient quantities to satisfy our clinical trial and commercial needs; the anticipated benefits of our ATEVs relative to existing alternatives; our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines; our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding our ongoing or planned clinical trials; the anticipated characteristics and performance of our ATEVs; the implementation of our business model and strategic plans for our business; our ability to execute and achieve the expected benefits of our cost-saving measures and whether our efforts will result in further actions or additional asset impairment charges that adversely affect 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, competitive and/or reputational 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, 2024 and Form 10-Q for the quarter ended March 31, 2025, 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

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