



Humacyte Announces FDA Authorization Extending Symvess Shelf Life to 36 Months

– FDA authorizes extension of Symvess expiration dating from 18 months to 36 months –

– Extended shelf life supported by additional stability data demonstrating Symvess continues to meet all established quality specifications throughout the 36-month dating period –

DURHAM, N.C., Sept. 09, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology company that develops bioengineered human tissues, today announced that the U.S. Food and Drug Administration (FDA) has authorized an extension of the expiration dating period for [Symvess](#)® (acellular tissue engineered vessel-tyod, or ATEV) from 18 months to 36 months when stored refrigerated at 2°C to 8°C (36°F to 46°F).

The expiration dating extension is supported by additional stability data demonstrating that Symvess continues to meet all established product quality specifications throughout the extended 36-month dating period when stored under approved conditions. The extended shelf life helps hospitals keep Symvess on hand for urgent vascular repairs while simplifying inventory planning and reducing product waste.

"This FDA authorization represents an important advancement in supporting the commercial availability of Symvess for hospitals and healthcare systems," said Laura Niklason, MD, PhD, Founder, President and Chief Executive Officer of Humacyte. "Extending the shelf life to 36 months provides greater inventory flexibility while maintaining the same storage requirements and approved clinical use. We believe this enhancement will further facilitate hospital adoption and ensure surgeons have access to Symvess when urgent vascular repair is needed."

Symvess was approved by the FDA in December 2024 as a vascular conduit for adults with extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss and an autologous vein graft is not feasible. As a first-in-class, off-the-shelf bioengineered human tissue, Symvess is available for use on-demand in the operating room, sparing surgeons the time required to harvest a vein from the patient and avoiding a second surgical site on a patient who is often already critically injured. Humacyte expects to file a supplemental Biologics License Application during November 2026, seeking to add dialysis access as the second approved indication for the ATEV.

For uses other than the FDA approval in the extremity vascular trauma indication, Symvess is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

To learn more about Symvess and Humacyte's pioneering bioengineered vascular technologies, visit [Symvess.com](#).

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 $\geq 10\%$), were vascular graft thrombosis, pyrexia (fever) and pain.

Please see full Prescribing Information at [symvess.com](https://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.

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; 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 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, 2025 and the Form 10-Q for the quarter ended June 30, 2026, each as 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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