



## Humacyte Announces Planned Marketing Authorization Application for Symvess® in Israel

- Expansion plans are based on requests for product access received from surgeons and hospitals in Israel -
- Expansion of Symvess into other territories, including those in Europe and the Middle East, is also planned -

DURHAM, N.C., Jan. 05, 2026 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced that it plans to file a Marketing Authorization Application (MAA) with the Israel Ministry of Health for approval of the acellular tissue engineered vessel (ATEV™ or Symvess) for arterial trauma repair during the first quarter of 2026. The Company currently expects that the MAA will be evaluated by the Ministry of Health in a review period of 120 working days due to the existing Food and Drug Administration (FDA) approval of Symvess. Humacyte is working in coordination with Israeli surgeons who participated in the V005 Phase 2/3 trial of Symvess in vascular trauma and who are petitioning the Ministry of Health seeking access to the product.

"Feedback from surgeons and hospitals support the need for Symvess in Israel, and we are pleased to be moving aggressively forward with our planned MAA filing this quarter," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "Israel represents just our first step in the global expansion of Symvess as we expect that our FDA approval enables expedited commercialization pathways in other territories, including those in Europe and the Middle East. We plan to report further expansion plans for Symvess based on the high level of interest we are receiving from healthcare providers in these regions."

Recently published positive three-year results from the V005 Phase 2/3 study of Symvess in extremity vascular repair represent the first-ever prospective long-term data in traumatic arterial repair using an off-the-shelf biologic conduit. Vascular trauma wounds are challenging for surgeons to treat, and autologous vein grafts have traditionally served as the standard of care due to their durability and low infection rates. However, autologous grafts are not always feasible in trauma settings where veins are damaged or there is little time to harvest. Symvess is designed to be immediately available off-the-shelf — saving critical surgical time in emergency situations — and has also consistently demonstrated low rates of infection and high rates of limb salvage.

### 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](http://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 September 30, 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](mailto:jallaire@lifesciadvisors.com)  
[investors@humacyte.com](mailto:investors@humacyte.com)

**Humacyte Media Contact:**

Rich Luchette  
Precision Strategies  
+1-202-845-3924  
[rich@precisionstrategies.com](mailto:rich@precisionstrategies.com)  
[media@humacyte.com](mailto:media@humacyte.com)



Source: Humacyte, Inc