Humacyte Submits Supplemental Biologics License Application to FDA for the Acellular Tissue Engineered Vessel in Dialysis Access

–sBLA submission seeks to add arteriovenous access for hemodialysis as second approved indication for the ATEV.

–sBLA supported by results from three Phase 3 studies in hemodialysis access.

–"For too long, patients on dialysis, and women in particular, have had to settle for access options that often do not work well for them. We are excited about the potential of the ATEV to provide a new potential vascular access option for hemodialysis patients in need," said Laura Niklason, M.D., Ph.D., Co-Founder and Chief Executive Officer of Humacyte.

DURHAM, N.C., Nov. 19, 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 has submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for the acellular tissue engineered vessel (ATEV) seeking approval in arteriovenous (AV) access for hemodialysis in patients with end-stage kidney disease (ESKD) who are at an increased risk of AV fistula maturation failure. The sBLA seeks to add hemodialysis access as the second approved indication for the ATEV following the FDA approval of the ATEV under the brand name Symvess® in December 2024 for the extremity vascular trauma indication.

In the recently reported V012 Phase 3 trial, women implanted with the ATEV achieved functional access more than three months sooner and spent significantly more time free of dialysis catheters over the first year than women who received an AV fistula, which is the current standard of care for hemodialysis access across all patients. Women have historically had poorer outcomes with AV fistula procedures, including higher rates of maturation failure, longer times to functional access, and greater reliance on infection-prone catheters. If approved, the ATEV would represent the first new option for patients needing alternative hemodialysis access options in decades. The proposed utilization of the ATEV in dialysis access would provide the near-term availability of a ready-to-use biologic conduit that has been observed to perform predictably in patients with small vessel anatomy, diabetes, obesity, or other factors that complicate AV fistula maturation. The ATEV represents a new option for many of the nearly 500,000 Americans currently dependent on hemodialysis for survival, offering a potentially safer and more reliable path to hemodialysis access.

"Submission of our sBLA for ATEV in hemodialysis access is a significant milestone for Humacyte and an important step toward giving patients on dialysis a potential new access option," said Laura Niklason, M.D., Ph.D., Co-Founder and Chief Executive Officer of Humacyte. "I want to thank the patients and medical professionals who participated in our three Phase 3 clinical studies, and our Humacyte team for their tremendous effort and dedication in completing the sBLA submission. We believe the ATEV has the potential to address a significant unmet need for patients who depend on hemodialysis, and we look forward to working closely with the FDA during its review. For too long, patients on dialysis, and women in particular, have had to settle for access options that often do not work well for them, leaving many reliant on infection-prone catheters. We are excited about the potential of the ATEV to provide a new potential vascular access option for patients in need."

The FDA has a 60-day review period to determine whether the sBLA is complete and acceptable for filing, as well as to set a timeline for their review. Humacyte has requested Priority Review of the application. The ATEV for AV access in hemodialysis received the FDA's first Regenerative Medicine Advanced Therapy (RMAT) designation and Fast Track designation.

The sBLA submission follows the presentation of breakthrough top-line interim results from the V012 Phase 3 trial in female dialysis access patients at the American Society of Nephrology's (ASN) *Kidney Week* 2026 in October 2026 and at the Society of Vascular Surgery's (SVS) Vascular Annual Meeting (VAM) in June 2026. Results from the V012 study showed that the ATEV outperformed autologous arteriovenous (AV) fistula, the current standard of care for patients on dialysis. The sBLA is also supported by efficacy and safety results from the comprehensive V007 and V006 studies, two previously completed Phase 3 studies of the ATEV in male and female dialysis access patients.

"This submission brings us one step closer to our goal of providing a new vascular access option for patients on hemodialysis," Niklason said. "We look forward to the FDA's review and remain focused on the opportunity to make a meaningful difference for patients in need of vascular access."

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; 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, 2025 and Form 10-Q for the quarter ended September 30, 2026, 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

