Humacyte Confirms Plans for ATEV Supplemental BLA Filing for Dialysis Access Following FDA Discussions

– Supplemental Biologics License Application (BLA) expected to be filed with the Food and Drug Administration (FDA) in November 2026 –

– Supplemental BLA will be supported by results from three Phase 3 studies of ATEV, including results from V012 dialysis access study in women –

– The V012 dialysis access study found that women who received Humacyte's ATEV experienced an average of three more months without a dialysis catheter than women who received AV fistula, the current standard of care –

DURHAM, N.C., Aug. 24, 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 recent discussions with the FDA confirm the Company's plans and expectations for filing a supplemental Biologic License Application (BLA) with the FDA for the acellular tissue engineered vessel (ATEV) in dialysis access. Humacyte expects to file the supplemental BLA during November 2026, seeking to add dialysis access as the second approved indication for the ATEV after its December 2024 FDA approval in the vascular trauma indication.

"Our recent discussions with the FDA, in which we shared clinical results and our filing plan, reinforce our confidence in the regulatory path forward for the ATEV in dialysis access," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "The positive Phase 3 clinical results we have seen to date, including the breakthrough outcomes recently reported in women from the V012 study, support our belief that the ATEV has the potential to address significant unmet needs for patients who currently have had to settle for access options that often don't work well for them. We look forward to submitting our supplemental BLA in November, and to continuing working closely with the FDA as we seek to expand access to this first-in-class product."

The planned supplemental BLA filing follows the presentation of breakthrough top-line interim results from the V012 Phase 3 trial in female dialysis access patients at the Society of Vascular Surgery's (SVS) *Vascular Annual Meeting (VAM)* in June 2026. Results from that study showed that the ATEV outperformed autologous arteriovenous (AV) fistula, the current standard of care for patients on dialysis. The supplemental BLA filing will also be 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.

The utilization of the ATEV in dialysis access represents the near-term availability of a ready-to-use biologic conduit that performs predictably in patients with small vessel anatomy, diabetes, obesity, or other factors that complicate AV fistula maturation. This is a significant option for the nearly 500,000 Americans currently dependent on hemodialysis for survival, offering a safer and more reliable path to dialysis access.

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.

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; the timing and expected benefits of the commitment to purchase Symvess to facilitate a clinical evaluation and outreach program in the KSA; our ability to realize the benefits of the DoD's funding in the DoD Appropriations Act; 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, 2025 and Form 10-Q for the quarter ended June 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.

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