Humacyte Announces Expansion of Intellectual Property for Pipeline Products with Granting of New U.S. Patent for Bioengineered Esophagus

– Patent covers esophagus produced using Humacyte's proprietary bioengineered regenerative tissue platform, designed for implant in patients with damaged esophagus –

– Patent provides coverage into 2041 for the composition of novel bioengineered esophagus –

DURHAM, N.C., Sept. 29, 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 allowance of a U.S. Patent covering the composition of a bioengineered esophagus that can be produced using the Company's proprietary regenerative tissue engineering platform. The patent, titled "Tubular Prostheses (Esophagus)," provides protection into 2041 of key structural and mechanical attributes for its designed use as an esophageal replacement including size, strength, and methods of production. Humacyte's Tubular Prostheses patent family encompasses composition and methods claims for advanced tissue constructs intended to replace damaged airways, upper digestive, and urinary tracts in patients.

"Bioengineered trachea, esophagus, and urinary conduits represent novel treatment programs that target high unmet patient needs as well as highlight the versatility of our regenerative tissue engineering platform and the breadth of our product pipeline," said Rob Kirkton, Ph.D., Executive Director of New Product and Process Development at Humacyte. With the most recent grant of patent, Humacyte has now secured coverage for composition of matter for bioengineered trachea, esophagus, and urinary conduits in the United States, Europe, Canada, and Australia. This represents an important expansion of the patent coverage for Humacyte's platform.

Advanced tissue constructs for tracheal, esophageal, and urinary conduit replacement have been evaluated in early preclinical models with plans for future optimization and testing in large animal models. The advanced tissue construct product candidates are one component of Humacyte's broad product pipeline that also includes acellular tissue engineered vessels (ATEV™), Coronary Tissue Engineered Vessels (CTEV) and the BioVascular Pancreas™ (BVP™). Each of these products can be produced using the same bioengineering technology and manufacturing platform as Humacyte's Symvess™ product.

"We are pleased to continue to expand the protection surrounding our bioengineered tissue platform and related novel product candidates," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "We plan to align ourselves with corporate partners where appropriate to accelerate the development of these programs."

The esophageal replacement and other advanced tissue constructs are investigational products and have 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 initial product candidates, a portfolio of acellular tissue engineered vessels (ATEVs), are currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous (AV) access for hemodialysis, and peripheral artery disease. A Biologics License Application for the ATEV in the vascular trauma indication was approved by the FDA in December 2024. 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 an 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 and our advanced tissue constructs 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 and our advanced tissue constructs; 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 June 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.

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