Humacyte Announces Allowance of U.S. Patent Covering BioVascular Pancreas (BVP™)

- New U.S. patent covers the design and composition of the BVP -

- Positive results from ongoing preclinical studies support the potential of the BVP to deliver insulin-producing islets as a potential treatment for type 1 diabetes -

DURHAM, N.C., Sept. 19, 2024 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, today announced the allowance of a U.S. Patent covering its BioVascular Pancreas (BVP) product candidate for the treatment of type 1 diabetes. The BVP is designed to enable the delivery and survival of insulin-producing islets inside the body, using Humacyte's investigational acellular tissue engineered vessel (ATEV™) as a carrier for the islets. The newU.S. Patent, titled "Bioartificial Vascular Pancreas," covers the design and composition of the BVP. The patent is owned by Yale University and is exclusively licensed to Humacyte.

Approximately 1.45 million Americans are currently living with type 1 diabetes, with 64,000 more Americans diagnosed each year. The incidence of type 1 diabetes is on the rise worldwide, impacting the lives of millions and causing significant economic burden. The disease requires constant vigilance and measurement of blood sugars, with patients having to continuously balance insulin intake throughout the day. While insulin management can regulate blood glucose levels and keep people alive, continuous and lifelong monitoring of blood sugar is difficult for patients who have no islets of their own to automatically control blood sugar levels.

The BVP is designed to enable the delivery and survival of insulin-producing islets inside the body. Such technology could overcome many of the hurdles currently associated with implantation of islets into diabetic patients. In June 2024, Humacyte reported positive results from two sets of ongoing preclinical studies, supporting the potential of the BVP product candidate to deliver insulin-producing islets as a treatment for type 1 diabetes. At a presentation at the Breakthrough T1D *Beta Cell Consortium Meeting*, Humacyte's scientists presented data in which stem cell-derived islets restored normal blood sugar in diabetic mice. Islets manufactured from human stem cells may provide the basis for the islets that are ultimately delivered using the BVP product candidate. At the American Diabetes Association annual meeting, Humacyte reported successful implantation of BVPs into non-human primate recipients. In the study, primate BVP implants showed islet survival and continued insulin production throughout the three-month duration of the study. Islets also developed capillaries to support survival of the insulin-producing cells.

"The recent presentations of preclinical results highlight the potential of the BVP to improve the care of patients with type 1 diabetes, and we look forward to continuing advancement of this important initiative aimed at treating patients with a profoundly debilitating disease," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "As development has progressed, we are pleased to achieve, in collaboration with Yale University, this major milestone in the U.S. patent protection of our BVP product candidate."

The ATEV and BVP are investigational products and have not been approved for sale by the Food and Drug Administration or any international 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 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 is currently under review by the FDA and was granted Priority Review. 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.

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, the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials, including our BVP program; the anticipated characteristics and performance of our ATEV and the BVP; our ability to successfully complete preclinical and clinical trials for our ATEVs and the BVP; the anticipated benefits of the BVP relative to existing alternatives; the anticipated commercialization of our ATEVs and our ability to manufacture at commercial scale; 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, 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, 2023, 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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