Humacyte Presents Positive Preclinical Data For Its BioVascular Pancreas (BVP™) Program

– BioVascular Pancreas (BVP) product candidate is under development as a potential treatment for type 1 diabetes –

– Humacyte's stem cell-derived islets observed to restore normal blood glucose in diabetic mice –

– Non-human primate models of BVP implantation showed islet survival and continued insulin production –

DURHAM, N.C., June 25, 2024 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, announced the presentation of positive preclinical progress of its development of a potential treatment for type 1 diabetes at two scientific meetings. Humacyte's BioVascular Pancreas (BVP) product candidate, currently in preclinical testing, incorporates stem cell-derived islets that are delivered using Humacyte's acellular tissue engineered vessel (ATEV) technology.

At a presentation at the Breakthrough T1D (formerly, JDRF) Beta Cell Consortium Meeting in New York City, scientists presented data in which stem cell-derived islets, manufactured at Humacyte, were observed to restore normal blood sugar in diabetic mice. In the mice, the stem cell-derived islets survived and continued to produce insulin, with no evidence of adverse safety events from the stem cell-derived islets. These experiments were performed in collaboration with the Diabetes Research Institute (DRI) at the University of Miami.

In addition, Humacyte scientists reported at the American Diabetes Association annual meeting in Orlando, Florida, successful implantation of BVPs into non-human primate recipients. In the study, also performed in collaboration with the DRI, Humacyte's ATEVs were coated with primate islets and were implanted into primate recipients. The 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. Humacyte has commenced preclinical studies in diabetic non-human primate models to further advance development of the BVP as a potential treatment for type 1 diabetes.

Dr. Laura Niklason, Humacyte's CEO, commented "We are extremely pleased with the preclinical progress in our BVP program. Our partners at the Diabetes Research Institute, along with our outstanding scientists and corporate partners, are showing the potential feasibility of the BVP concept, which one day may help thousands of patients with severe type 1 diabetes."

The BVP is regenerative medicine product candidate that designed to support pancreatic islet transplantation into patients with type 1 diabetes. The BVP combines islets with Humacyte's investigational ATEV. Current methods of islet administration rely upon islets that are injected into the portal vein of the liver, a procedure that has produced therapeutic benefit for some patients but has deficiencies in engraftment of islets. The BVP is designed to supply the necessary oxygen to transplanted islets and support their successful engraftment into patients.

The BVP and ATEV 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 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 is currently under review by the FDA and was granted Priority Review with a PDUFA date of August 10, 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 RMAT designation and has also received FDA Fast Track designation. Humacyte's 6mm ATEV for urgent arterial repair following extremity vascular trauma also has received an RMAT designation. 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 expected PDUFA date for our ATEV in vascular trauma repair; 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 ATEVs 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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