Humacyte and Pluristyx Announce Gene Editing Partnership to Support BioVascular Pancreas (BVP™) Development Using iPSCs

DURHAM, N.C.and SEATTLE, Jan. 28, 2025 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, and Pluristyx, Inc. today announced an expanded partnership. Pluristyx makes and sells PluriBank™ iPSC lines as part of their tools, technologies, and services to support the development of cellular therapies, and is currently performing gene editing of PluriBank cells for Humacyte's use in developing its investigational BioVascular Pancreas (BVP™), designed for the potential treatment of insulin-dependent diabetes.

Pluristyx has developed a clinical-grade manufacturing process for using a licensed Mad7 gene editing technology to block Human Leukocyte Antigen (HLA) markers expression. Humacyte is optimizing a process to differentiate immune-evading iPSCs, provided by Pluristyx, into a pancreatic islet component of their BVP that will aim to normalize glucose levels in diabetic patients. The expanded partnership builds on Humacyte's existing license for Pluristyx's PluriBank cell lines.

"We are excited to grow our pipeline by advancing the development of the BVP, an advanced tissue and organ system," said Laura Niklason, M.D., Ph.D., Founder and Chief Executive Officer of Humacyte. "The stem cell and gene editing technologies from Pluristyx have promising advantages for our BioVascular Pancreas and other cell and tissue therapies."

"The recent FDA approval for Humacyte's Symvess™ (acellular tissue engineered vessel) for use as a vascular conduit for extremity arterial injury is a huge step forward to treating trauma patients," said Benjamin Fryer, Ph.D., co-Founder and Chief Executive Officer of Pluristyx. "Pluristyx is proud to support Humacyte as they develop the BioVascular Pancreas, a highly needed organ system for the treatment of insulin-dependent diabetes."

The BVP is designed to enable the delivery and survival of insulin-producing islets inside the body, using Humacyte's acellular tissue engineered vessel (ATEV™) as a carrier for the islets. The BVP is an investigational product in pre-clinical development and has not been approved for sale by the Food and Drug Administration or any global regulatory agency.

About Pluristyx

Pluristyx is a privately held, biotechnology company offering a wide range of products and services to support the development and manufacture of cell and gene therapies, including iPSC lines, proprietary genetic engineering technologies, differentiation services, iPSC culture kits, and contract development services. Pluristyx is committed to delivering highest quality products and services to accelerate clinical translation of life-changing cell therapies. For more information on Pluristyx visit www.pluristyx.com.

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. 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 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. For more information, visit www.Humacyte.com.

Humacyte 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; the anticipated characteristics and performance of our ATEV; our ability to successfully complete preclinical and clinical trials for our ATEVs and the BVP; the anticipated benefits of the our BVPs relative to existing alternatives; the expected success of our sales team; the validity of our Budget Impact Model; 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 subsequent 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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