Humacyte Completes Enrollment in Phase 3 Trial of Human Acellular Vessel™ (HAV™) fo Hemodialysis Access in End-Stage Renal Disease Patients

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DURHAM, N.C., April 11, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced it has completed enrollment of a Phase 3 trial in hemodialysis access. The "V007 Trial" is designed to assess the efficacy and safety of the Human Acellular Vessel (HAV) in establishing vascular access for hemodialysis patients with end-stage renal disease (ESRD) as compared to autogenous arteriovenous (AV) fistulas.

The Phase 3 trial, labeled V007, is a prospective, multi-center, randomized, comparative study in 240 hemodialysis patients suffering from ESRD in the United States. Enrolled individuals were randomly assigned to either the HAV, or an AV fistula for hemodialysis. Efficacy assessments includ useability of the conduit for dialysis at six and 12 months and a comparison of secondary patency, evaluated at 12 months. The rate of dialysis-related infections in both HAV and fistula subjects will also be tracked as a secondary endpoint.

"Completing enrollment in this Phase 3 trial brings us one step closer to our goal of providing vascular access for dialysis patients that is usable more quickly after implant and reduces reliance on catheters, compared to AV fistula procedures," said Shamik Parikh MD, Chief Medical Officer at Humacyte. "We believe our regenerative medicine technology has the potential to transform the quality of care nephrologists are able to provide to their patients, and address the substantial failure rate and risk of infection associated with the current AV access options for hemodialysis."

Nearly 786,000 Americans are currently living with ESRD, a disease that develops when chronic kidney disease progresses to a point where either dialysis or a kidney transplant is required for survival. Dialysis treatments require establishing a durable point of access to a patient's circulatory system, in order to transfer the large volume of blood that must be transported to the dialysis machine and then back into the patient.

However, the current standard of care for establishing vascular access has significant risks and shortcomings. Catheters, which are tunneled underneath the skin, have high rates of bloodstream infection, while autogenous AV fistulas exhibit a high rate of early maturation failure, forcing patients to rely longer on infection-prone catheters. In addition, many patients are not suitable candidates for fistula placement due to small vessel anatomy, advanced age, obesity, or other comorbidities.

Humacyte's HAV is a universally implantable, durable tissue-engineered vascular conduit that is designed to be highly resistant to infection and, over time, has been observed to combine with a patient's own cells to create a living blood vessel. Utilized for AV access, the HAV has the potential to be usable for dialysis more rapidly after implant, and result in reduced time on catheters which pose an infection risk for patients, than an AV fistula procedure.

Dr. John Lane, vascular surgeon at VA San Diego and V007 investigator comments, "My experience with the use of the Human Acellular Vessel in our VA population has been very positive thus far. Being involved with the clinical trial has allowed us to provide patients with the latest and greatest in technology, and hopefully gives a window into what will be in the future for hemodialysis access."

Hear more from Dr. Lane around his impressions of the HAV and its use in the field of hemodialysis access in this short video: https://bit.ly/DrLaneV007

The Phase 3 V007 trial builds on Humacyte's series of clinical trials designed to support the use of the HAV technology to expand hemodialysis treatment options. The Company's 6mm HAV for AV access for hemodialysis was the first product candidate to receive the FDA's Regenerative Medicine Advanced Therapy (RMAT) designation in 2017 and was awarded an FDA Fast Track designation in 2014.

The HAV 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 initial opportunity, a portfolio of Human Acellular Vessels (HAVs), is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous access for hemodialysis, and peripheral arterial 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 HAV for arteriovenous (AV) access for performing 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. The HAV 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, statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our HAVs; our ability to successfully complete, preclinical and clinical trials for our HAVs; the anticipated benefits of our HAVs relative to existing alternatives; the benefits and risks related to our humanitarian efforts in the Ukraine; the anticipated commercialization of our HAVs and our ability to manufacture at commercial scale; the implementation of our business model and strategic plans for our business; our rights and obligations under our partnership with Fresenius Medical Care; the scope of protection we are able to establish and maintain for intellectual property rights covering our HAVs and related technology; the timing or likelihood of regulatory filings and approvals; timing, scope, and rate of reimbursement for our HAVs; the outcome of our ongoing discussions with the FDA concerning the design of our ongoing V005 Phase 2/3 clinical trial, including determination of trial size, and the scope of any approved indication for our HAVs; and our estimated available market opportunity. 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, the impact of COVID-19 on Humacyte's business, and other risks and uncertainties, including those included under the header "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, 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. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. 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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