Humacyte Completes Enrollment in Phase 2/3 Trial of Human Acellular Vessel™ (HAV™) for Vascula Trauma Repair

-Top-line results planned to be released in third quarter 2023-

-Trial results are intended to support Biologics License Application (BLA) planned for fourth quarter 2023-

DURHAM, N.C., July 26, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced completion of enrollment of its Phase 2/3 vascular trauma trial (V005) that is expected to support a BLA filing for Humacyte's HAV in vascular trauma repair. The HAV, an innovative regenerative medicine product candidate, is designed to provide surgeons with an off-the-shelf bioengineered human artery that has been observed to repopulate with the patient's own cells to provide a durable, infection-resistant replacement for damaged and diseased arteries. The HAV has the potential to assist healthcare professionals in saving life and limb in some of the most difficult circumstances. The results from the Phase 2/3 vascular trauma trial are intended to support a BLA filing with the Food and Drug Administration (FDA), planned for the fourth quarter 2023.

The V005 trial is a single-arm, open-label, pivotal study of patients suffering from vascular trauma injuries, conducted at Level 1 Trauma Centers in the U.S. and Israel. The primary efficacy assessment will be based on a 30-day HAV patency (presence of blood flow) in patients who have vascular trauma of the extremity, as compared to historic benchmarks reported in literature. Humacyte, the clinical trial sites, and contracted service providers are preparing for locking of the trial database in order to report the V005 results. The Company currently expects to complete these activities and report top-line results from the trial before the end of the third quarter 2023.

"We believe that the HAV could revolutionize the ability of surgeons to save the lives and limbs of patients suffering vascular injuries, not only in civilian settings, but also in more challenging environments like the battlefield," said Dr. Laura Niklason, CEO of Humacyte. "The completion of the target enrollment in Humacyte's Phase 2/3 vascular trauma trial is expected to enable BLA submission, and is another important landmark moment for our groundbreaking science. Our regenerative medicine technologies create dramatic new therapies – with the potential to provide treatment options for patients facing loss of life or limb for whom current therapies are either inadequate or not available."

Treating traumatic injuries, such as those occurring with car accidents or gunshot wounds, can be especially challenging due to the severity of the injury, the risk of infection, and the need to treat the patient quickly to avoid loss of life or limb. Under current practices, surgeons often harvest a vein from the patient's leg, which requires additional time and expert training for the surgeon. The incision, pain, and wound complications associated with cutting into the leg to remove a vein also cause difficulties for patients and caregivers. Current off-the-shelf alternatives to veins, such as plastic vessel grafts, are highly prone to infection and so are not used very often for treating trauma patients.

Humacyte's HAV is a universally implantable, bioengineered human artery that is designed to overcome these challenges. It is available to the surgeon immediately, and eliminates the need to harvest and repurpose a vein. Because it is off-the-shelf, the HAV can ultimately save valuable time and potentially reduce complications like amputations and tissue loss. Because the HAV is comprised of the same tissue that makes up natural human vessels, it has the potential to repopulate with the patient's own cells. Clinical results suggest that the HAV is highly infection-resistant and therefore is well suited for treating the contaminated wounds created by major traumatic injuries. Importantly, the HAV can be produced at commercial scale in Humacyte's existing manufacturing facilities, providing thousands of vessels for treating injured patients.

The V005 study is intended to support Humacyte's BLA filing with the FDA for treatment of extremity vascular trauma when a synthetic graft is not indicated and when an autologous vein is not feasible. The completion of V005 enrollment comes on the heels of Humacyte receiving the FDA's Regenerative Medicine Advanced Therapy (RMAT) designation for the HAV in vascular trauma in May 2023. The RMAT designation allows for close collaboration between Humacyte and the FDA, and increases the chance for a priority review of a BLA after it is filed. At the time of V005 target enrollment, a total of 68 patients had received the HAV in the V005 trial, of which 51 had vascular trauma of the extremity and comprise the primary efficacy analysis.

In addition to the V005 trial, the HAV is also being used in Ukraine under a humanitarian aid program that has treated 19 vascular trauma patients in the ongoing war, demonstrating a high rate of favorable outcomes in treating some of the most difficult and infection-prone vascular injuries. The data from the Ukraine humanitarian program will be included in the BLA filing with the FDA. The HAV has accumulated more than 1,000 patient-years of experience worldwide in a series of clinical trials in multiple indications, including vascular trauma, arteriovenous access for hemodialysis, and peripheral artery disease.

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 HAVs, is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, AV 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 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 HAV for urgent arterial repair following extremity vascular trauma also has received RMAT 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 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; 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, 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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