Humacyte Announces Publication of Preclinical Study Comparing Human Acellular Vessel™ (HAV ™) to Expanded Polytetrafluoroethylene (ePTFE) Graft in Vascular Trauma

April 18, 2023

Results published in Journal of Trauma and Acute Care Surgery

Company also provides update on enrollment progress in Phase 2/3 vascular trauma trial

DURHAM, N.C., April 18, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, announced the publication of a preclinical study in the *Journal of Trauma and Acute Care Surgery* comparing the use of its Human Acellular Vessel (HAV) to expanded polytetrafluorethylene (ePTFE) grafts for vascular repair following arterial trauma. In the preclinical study the HAV performed better than ePTFE on multiple indices.

In this comparative preclinical study, 36 pigs were randomly assigned to treatment groups receiving either the HAV or an ePTFE graft to reconstruct a severed iliac artery after vascular trauma. The animals were monitored for 28 days and routinely assessed for recovery of hind limb function, graft patency, and circulating biochemical markers of tissue ischemia and reperfusion injury. At the conclusion of the study, the HAV and ePTFE implants were removed and histologically evaluated for host cellular response.

The data observed in this preclinical study indicate that the HAV performed better than ePTFE on multiple indices, including recovery of limb function after six hours of ischemia and conduit patency. In addition, the HAV showed no incidence of infection, degradation, aneurysm or mechanical failure. Host recellularization of the HAV conduits was observed to be greater than that of ePTFE grafts.

If not treated quickly and correctly, vascular trauma can lead to amputation or death. The standard practice for vascular repair requires harvesting and repurposing a section of vein from another limb, a process that can be time-consuming, painful, and may lead to failure or other complications for the patient. Alternatively, synthetic grafts like ePTFE have been shown to lack positive host responses and recellularization, making ePTFE more prone to infection and hence often unsuitable for contaminated wounds.

“We believe the results of this study underscore the potential of the HAV to save the lives and limbs of those suffering from vascular injury and peripheral tissue ischemia,” said Rob Kirkton, Ph.D., Director of New Product Development at Humacyte and lead author of the publication.

Humacyte’s HAV is a universally implantable and an infection-resistant vascular conduit that is designed to avoid the difficulties and increased recovery time associated with harvesting a vein. The HAV is also designed to resist infection, making it potentially useful in contaminated wound beds or other settings at high risk for infection. Additionally, the HAV is intended to be ready off-the-shelf and available whenever surgeons need it, saving valuable time and potentially improving patient outcomes in cases requiring urgent vascular repair for both civilians and military personnel.

The publication of this preclinical study comes as Humacyte nears the completion of enrollment in its Phase 2/3 V005 clinical trial of the HAV in the repair of vascular trauma. The primary efficacy assessment of the HAV will be based on a 30-day patency in 50 patients from the V005 trial who have vascular trauma of the extremity (excluding torso injuries and iatrogenic trauma patients). Currently, a total of 65 patients have received the HAV in the V005 trial, including 48 patients comprising the primary endpoint population. The Company plans to enroll approximately four more patients in the trial to support a Biologics License Application (BLA) filing for accelerated approval with the U.S. Food and Drug Administration (FDA). In addition, the product candidate is also being used under a humanitarian program for which 18 vascular trauma patients wounded in the ongoing conflict in Ukraine have been treated with the HAV. The HAV has accumulated over 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 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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