Humacyte Publication in the Journal of Vascular Surgery – Vascular Science Reports the Human Acellular Vessel™ (HAV™) Remains Durable at Six Years in Patients with Peripheral Artery Disease

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- HAVs observed to provide long-term perfusion to patients with critical limb ischemia

- 3D Angiograms show mechanical durability of engineered human blood vessels

DURHAM, N.C., Jan. 24, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissues and advanced tissue constructs and organ systems at commercial scale, today announced the publication of "6-Year Outcomes of a Phase 2 Study of Human-Tissue Engineered Blood Vessels for Peripheral Arterial Bypass," in the *Journal of Vascular Surgery – Vascular Science*. The publication describes the long-term analysis of the Company's Phase 2 clinical trial evaluating the bioengineered HAV as a conduit in patients with symptomatic peripheral artery disease (PAD). The researchers concluded that "the infection-resistant, off-the-shelf human acellular vessel could provide a durable alternative conduit in the arterial circuit setting, to restore lower extremity blood supply in patients with peripheral artery disease."

This paper reports that the overall secondary patency rate for the Phase 2 study at 72 months, including all patients originally enrolled, was estimated by Kaplan Meier analysis to be 60%. There was no evidence of graft rejection or infection. Additionally, no patients underwent amputation of the affected limb out to six years, a meaningful clinical and quality of life result as amputation is a common outcome in many severe PAD patients. No patients reported pain at rest or ischemic ulcers on the affected legs. Researchers reported that "these data have demonstrated the durability of the HAV and suggest the occurrence of cellular remodeling by the host."

Piotr Gutowski, M.D., Ph.D., Chief of Vascular Surgery, General Surgery and Angiology at Pomeranian Medical University and lead manuscript author, commented, "Synthetic grafts can be limited due to poorly matched mechanical compliance, risk of infection, and variable patency rates. Furthermore, cryopreserved allogenic grafts are limited due to poor durability, thrombosis, and mechanical degradation. The HAV is designed to be consistent in size, durable in high-pressure circulation, show no clinical immunological response, and remodel with the patient's own cells."

"With an increasing global prevalence of PAD and more than 200 million people living with the disease, there still remains a major unmet need for long-term solutions," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "Key findings of this publication show that the HAV was durable and performed well in a medically complex patient cohort for long-term treatment of PAD. The HAV is designed to be available off-the-shelf, has the potential for a regenerative capacity and low infection risk, all of which are particularly important in this patient group."

The HAV has been evaluated in eight clinical studies in the U.S., Europe, and Israel, including an ongoing Phase 2/3 clinical trial in vascular trauma and an ongoing Phase 3 trial as a hemodialysis access in end-stage kidney disease. The HAV is an investigational product and has not been approved for sale by the U.S. Food and Drug Administration or any international regulatory agency.

About HAV
Human Acellular Vessels (HAV) are investigational engineered off-the-shelf replacement vessels initially being developed for vascular repair, reconstruction and replacement. HAVs are intended to overcome long-standing limitations in vessel tissue repair and replacement – they can be manufactured at commercial scale, they eliminate the need for harvesting a vessel from a patient, and clinical evidence suggests that they are non-immunogenic, infection-resistant, and can become durable living tissue. The HAV is currently being evaluated in two Phase 3 trials in arteriovenous access and a Phase 2/3 trial for vascular trauma, and has been used in more than 500 patients. Humacyte's 6mm HAV for AV access for performing hemodialysis was the first product to receive Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA), and has also received FDA Fast Track designation. The HAV has received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense.

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.

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