Humacyte Announces JAMA Surgery Publication Highlighting Potential of Human Acellular Vessel™ (HAV™) to Expand Vascular Trauma Reconstruction and Bypass Treatment Options

June 29, 2022

-- HAV implanted in nearly 500 patients with more than 1,000 patient-years of follow up to date, for treatment of peripheral arterial disease, arteriovenous access for hemodialysis, and trauma –

-- Immediately-available HAV, if approved, would represent significant and innovative advancements for vascular repair and replacement conduits--

DURHAM, N.C., June 29, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced that an analysis of the potential of the Human Acellular Vessel (HAV) to expand vascular surgical treatment options has been published online in the *Journal of the American Medical Association* (JAMA) companion journal *Surgery*.

Humacyte's HAVs are engineered replacement vessels designed to be durable, infection-resistant and off-the-shelf to address long-standing limitations in vessel tissue repair and replacement. The HAV is currently being evaluated in late-stage clinical trials in vascular trauma repair, arteriovenous access for hemodialysis, and peripheral arterial disease (PAD). To date, the HAV has been implanted in nearly 500 patients, with more than 1,000 patient-years of follow up across seven clinical trials, including 31 cases performed under an authorized U.S. Food and Drug Administration's (FDA) Expanded Access Program (EAP).

The *JAMA Surgery* manuscript, entitled "The Human Acellular Vessel (HAV) for Vascular Reconstruction and Bypass," reviews the clinical need for improved options for vascular reconstruction and bypass conduits, and the potential advantages of the HAV over existing approaches.

"The current standard of care for vascular reconstruction or bypass procedures requiring a replacement vessel often involves autologous vein harvesting, which is associated with wound complications, or using a synthetic vascular conduit, which has demonstrated unfavorable compliance to native vessels," said Todd E. Rasmussen, M.D., FACS, (Col, ret. USAF MC), manuscript co-author, and Professor and Vice-Chair for education in the department of surgery and a senior associate consultant in the division of vascular and endovascular surgery at Mayo Clinic. "While there have been tremendous advancements in vascular surgery in the past few decades, the HAV represents the first recent innovation of a biologic vascular conduit that has the potential to make a significant impact on the clinical care of vascular disease and trauma. Additional clinical evaluation of the effectiveness and durability of the HAV is warranted and ongoing." Dr. Rasmussen has treated nearly 20 patients with the HAV as part of the EAP and in his leadership of ongoing clinical trials.

The *JAMA Surgery* manuscript also highlights clinical data in support of broadly leveraging the HAV in vascular surgical contexts in the future. This includes a Phase 2 trial of the HAV in patients with PAD, with no reported HAV-related infections, structural failures or amputations to date. Durability as a dialysis access conduit has also been observed, with the HAV tolerating and healing repeated needle punctures over time.

"The favorable data from multiple clinical trials and our surgical experience has indicated the HAV represents a promising regenerative medicine alternative conduit with favorable biologic properties, including durability and low risk of infection, with broad application," said first author Alexis L. Lauria, M.D., Uniformed Services University of the Health Sciences and Walter Reed National Military Medical Center in Bethesda, Md. "Further study of the HAV as a long-term conduit for vascular reconstruction and bypass, in many areas where arterial bypass has limited options, is warranted."

Results from the first series of compassionate use cases of the HAV for the treatment of critical limb ischemia were also recently published online in the *Annals of Vascular Surgery*. The manuscript, entitled "Preliminary Experience with the Human Acellular Vessel: A Descriptive Case Series Detailing Early Use of a Bioengineered Blood Vessel for Arterial Repair," reports early outcomes of HAV implantation into eight patients with complex limb ischemia and limited vascular conduit options who may have otherwise faced amputation, under an FDA-authorized EAP. The HAV remained patent in five patients who received lower extremity bypasses at an average of 11.4 months (range 4-20 months). The results were presented by Alexander Kersey, M.D., of the Uniformed Services University of the Health Sciences and Walter Reed National Military Medical Center at the 46th Annual Winter Meeting of the Vascular and Endovascular Surgery Society (VESS).

"Inadequate blood flow can quickly deteriorate to a possible limb loss scenario without a suitable vascular conduit replacement to restore circulation," said Dr. Kersey. "The case series demonstrated the HAV remained patent and infection-free and continued to function in patients with complex revascularization situations, further reinforcing the potential of the HAV to expand opportunities for limb salvage in vascular trauma and reconstruction."

"The *JAMA Surgery* and *Annals of Vascular Surgery* publications underscore the innovative nature of our bioengineered HAV, its potential advantages over current approaches, and the clinical progress we've made," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "We look forward to continuing to build upon this robust body of data supporting the versatility and potential of the HAV to improve life- and limb-saving clinical care."

The HAV is an investigational product and has not been approved for sale by the FDA 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. HAV is intended to overcome long-standing limitations in vessel tissue repair and replacement – it can be

manufactured at commercial scale, it eliminates the need for harvesting a vessel from a patient, and clinical evidence suggests that it is 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 nearly 500 patient implantations. 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 and complex tissue 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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