



Humacyte Provides Update on Patients Treated at Front-Line Hospitals in Ukraine with the Human Acellular Vessel™ (HAV™) for Repair of Vascular Trauma Injuries

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-- Successful first two HAV implantations in wounded Ukrainian citizens

-- HAVs were provided under Humacyte's initiative to assist Ukraine humanitarian medical effort

-- Provides further real-world evidence of the potential of HAV treatment for trauma

DURHAM, N.C., June 21, 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 the first Ukrainian patients have received implants of the Human Acellular Vessel (HAV) for the treatment of vascular trauma injuries. The implants are part of Humacyte's humanitarian relief initiative to provide investigational HAVs to multiple front-line Ukrainian hospitals for the treatment of patients with traumatic injuries.

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 first two Ukrainian patients -- one injured by shrapnel and the other by a gunshot wound -- received HAVs earlier this month and are being followed through their recovery. The Ukrainian patient who suffered a severe gunshot wound to the leg had already suffered a failed repair of his artery with a synthetic graft which became infected, and was at risk of limb loss. The HAV implantation restored blood flow to the injured leg.

"We're inspired by the dedicated and skilled physicians, nurses and medical staff who were trained on use of the HAV and are endeavoring to bring the innovative technology to Ukrainian patients in need," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "The HAV has demonstrated durability and infection resistance in multiple clinical trials across various vascular applications, and its off-the-shelf availability means it can be quickly employed in emergency vascular repair. We're honored to be able to contribute to the ongoing Ukraine medical relief work to help save the limbs and lives of patients during this conflict."

These patient cases provide real-time, real-world evidence supporting the use of the HAV in urgent trauma situations, including in active conflict scenarios. The HAV is being evaluated in a Phase 2/3 clinical trial in vascular trauma, when saphenous veins are not a good option or not available. The HAV has received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense. As the humanitarian effort in Ukraine progresses and patients are treated with the HAV, Humacyte continues to work alongside the Office of International Programs within the U.S. Food and Drug Administration (FDA) and the Ukrainian Ministry of Health. The HAV is an investigational product and has not been approved for sale by the FDA, the Ukrainian Ministry of Health, 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 more than 460 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.

Humacyte Investor Contact:

Joyce Allaire
LifeSci Advisors LLC
+1-617-435-6602
jallaire@lifesciadvisors.com
investors@humacyte.com

Humacyte Media Contact:

Heather Anderson
6 Degrees
919-827-5539
handerson@6degreespr.com
media@humacyte.com