Humacyte to Provide Human Acellular Vessels™ (HAVs™) to Front-line Hospitals in Ukraine fo Treatment of Vascular Trauma Injuries

-- First shipment of HAVs to six Ukrainian hospitals made today --

-- Product candidate to be used for civilian and military vascular trauma repair, the HAV's lead investigational indication --

DURHAM, N.C., May 09, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced the launch of an initiative to provide Human Acellular Vessels (HAVs) to multiple hospitals in Ukraine for the treatment of wounded civilians and soldiers with vascular injury, with the first shipment of HAVs departing the U.S. today. HAVs are engineered, off-the-shelf replacement vessels being developed for vascular repair, reconstruction and replacement.

Humacyte worked with the Office of International Programs within the U.S. Food and Drug Administration (FDA) as well as the Ukraine Ministry of Health to coordinate export and import of the investigational HAV for humanitarian use. Six hospitals in Ukraine, including in Kyiv, Kharkiv and other cities, will be the recipients of the initial shipment. Additional site requests are currently being processed.

"This initiative began as a request from one Ukrainian surgeon who was familiar with the HAV. Quickly, requests grew from other surgeons and sites around Ukraine. We continue to receive requests from local surgeons for the product candidate and plan to coordinate shipments to additional hospital sites as soon as possible," said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. "Humacyte is proud to contribute to the ongoing Ukraine medical relief and to support the patients and the brave medical providers on the ground during this humanitarian crisis. I'm immensely grateful to the Humacyte team for their tireless work seeing this through, as well as clinicians in Poland and the U.S. who have volunteered to assist in training Ukrainian physicians in the use of the HAV."

The HAV is being evaluated in a Phase 2/3 clinical trial in vascular trauma for use a vascular replacement to restore blood flow to a limb, when saphenous veins or synthetic grafts are not a good option. The HAV has received priority designation the treatment of vascular trauma by the U.S. Secretary of Defense. The HAV is an investigational product and has not been approved for sale by the FDA or any international regulatory agency.

"Our commercial manufacturing facility is already operational, which affords us the ability to provide these units while also meeting the requirements of our ongoing HAV clinical trials," said Dr. Niklason. "While outside the scope of our pivotal trauma trial, we expect this humanitarian effort will provide additional real-world evidence of the potential impact of the HAV in the treatment of vascular trauma injuries."

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.

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