



## **Humacyte Announces Presentations by Ukrainian Surgeons on Use of the Human Acellular Vessel™ to Treat Wartime Vascular Trauma at the European Society for Vascular Surgery Annual Meeting**

September 23, 2022

### **HAV™ was utilized to treat multiple patients suffering from shrapnel, gunshot wounds, and mine blast injuries**

DURHAM, N.C., Sept. 23, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissues, complex tissue systems, and organs at commercial scale, today announced the presentation of a clinical update on the Human Acellular Vessel (HAV) for the treatment of vascular trauma. The update was presented by Ukrainian surgeon collaborators, Oleksandr Sokolov, M.D., Ph.D. and Vasyl Shaprynskyi, M.D., Ph.D., at the 36<sup>th</sup> European Society for Vascular Surgery (ESVS) Annual Meeting in Rome, Italy taking place from September 20-23, 2022. Humacyte's investigational HAV is designed to offer off-the-shelf availability and resistance to infection and to address long-standing limitations in vascular tissue repair and replacement.

Dr. Shaprynskyi attended the conference in-person and presented a live talk entitled, "The First Experience of Using the Human Acellular Vessels in Ukraine for the Treatment of Patients with Vascular Trauma," while Dr. Sokolov spoke virtually from Ukraine and presented, "Vascular Trauma Due to Blast Injury. Experience of Dnipro in Russian-Ukrainian War 2022." Drs. Shaprynskyi and Sokolov have been instrumental in establishing their hospitals as medical strongholds during the Russian-Ukrainian war and reported that blast trauma, causing massive tissue damage and infected wounds, accounts for approximately 82% of incoming vascular trauma cases to their medical centers. Trauma to the extremities makes up the majority of injuries, primarily vascular injuries to the lower extremities and shoulders.

"Access to the HAV, a biologic conduit, has improved our ability to perform vascular reconstructions by eliminating the need to harvest a venous conduit and saving time required to look for useable vein, assisting greatly in limb salvation. While we continue to face this crisis in our country, partnerships with groups like Humacyte allow us to overcome many limitations in wartime medical care that we previously experienced such as lack of readily available conduits that are resistant to infection, particularly important in the contaminated battlefield setting," said Dr. Shaprynskyi.

Drs. Shaprynskyi and Sokolov reported that surgeons in Ukraine have utilized the HAV to treat patients with a multitude of wartime injuries. Dr. Sokolov provided a clinical update on a patient with a blast injury to the shoulder who received a repair using the HAV. The patient is now beyond three-month follow up without complication. Another patient who suffered a blast injury to the lower leg underwent successful HAV implantation and is now one-month past surgery without complication. Dr. Shaprynskyi reported on a patient with a gunshot wound to the right thigh that was initially treated with a synthetic graft, but ultimately the graft failed due to infection, putting the patient at risk of limb loss. The HAV was used to replace the infected graft, and three months later the HAV is supplying blood flow to the limb and is infection free.

Humacyte worked closely with the Office of International Programs of the U.S. Food and Drug Administration (FDA) and the Ukrainian Ministry of Health to provide the HAV as an additional treatment option to those affected with vascular injury in Ukraine. Humacyte is currently evaluating the HAV in a Phase 2/3 clinical trial in vascular trauma for use as a vascular replacement to restore blood flow to a limb, when saphenous veins or synthetic grafts are not feasible. The HAV has received priority designation for 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.

Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte, added, "As we progress in our humanitarian efforts with the HAV, being able to witness these firsthand patient cases from surgeons in Ukraine is a powerful experience. We set out to develop engineered replacement vessels that are durable, infection-resistant and off-the-shelf to address long-standing limitations in vessel repair, both for civilians and for military personnel. Given our existing designation as a Priority Product from the U.S. Department of Defense, it is gratifying to see that the HAV is helping patients suffering from wartime injuries in Ukraine right now."

### **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 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 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](http://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; 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, the impact of COVID-19 on Humacyte's business, changes in applicable laws or regulations, the possibility that Humacyte may be adversely affected by other economic, business, and/or competitive factors, 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, 2021, 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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