



Humacyte Announces Clinical Case Series Demonstrating Potential of Human Acellular Vessel™ (HAV™) to Expand Opportunities for Limb Salvage in Multiple Complex Vascular Reconstruction Scenarios

January 31, 2022

- Outcomes of first eight compassionate use cases presented at 46th Annual Winter Meeting of the Vascular and Endovascular Surgery Society –
- HAV observed to maintain patency and resist infection in the treatment of critical limb ischemia, infection and vascular trauma –
- All patients lacked suitable alternative conduit options –

DURHAM, N.C., Jan. 31, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced results from the first series of compassionate use cases of Humacyte's investigational Human Acellular Vessel (HAV) for the treatment of critical limb ischemia and vascular trauma. The HAVs were observed to remain patent and infection free in patients requiring vascular reconstruction, thereby highlighting the potential of the HAV to expand limb salvage options for patients who have exhausted current revascularization conduit options. These results were presented at the 46th Annual Winter Meeting of the Vascular and Endovascular Surgery Society (VESS).

Humacyte's HAVs are engineered replacement vessels being designed to be durable, infection-resistant and off-the-shelf to address long-standing limitations in vessel tissue repair and replacement. Under the U.S. Food and Drug Administration's (FDA) Expanded Access Program (EAP), the HAV has been implanted in more than 20 patients to address multiple severe vascular repair, reconstruction and replacement conditions when there is not a suitable conduit available for treatment.

The results of eight of these EAP patients were reported at the VESS meeting by Alexander Kersey, M.D., of the Uniformed Services University of the Health Sciences and Walter Reed National Military Medical Center in Bethesda, Md., in a presentation, titled, "Real World Experience with the Human Acellular Vessel: A Bioengineered Implant for Arterial Repair That Expands Limb Salvage Options." Each of the patients had severe peripheral arterial disease (PAD) or vascular injury requiring vascular reconstruction but lacked other treatment options and were at risk for limb loss. In this high-risk group of patients, five of the bypasses performed with the HAV currently remain patent (with follow-up times ranging from four to 20 months after surgery), and no incidences of infection of the HAV were noted. Researchers treating these patients concluded that the HAV may greatly expand opportunities for limb salvage in trauma and urgent vascular reconstruction when patients lack suitable alternative conduits.

"Many patients who require urgent vascular reconstruction due to vascular injury or severe peripheral arterial disease are not candidates for synthetic vascular grafts or autologous vein grafts, and those who've exhausted other treatment methods are at high risk of amputation," said Dr. Kersey. "There is considerable need for a new treatment option to avoid resorting to amputation, and results from these compassionate use cases merit additional research into the role the HAV may play in the future of limb-sparing surgery."

In addition to infection resistance and durable patency, the presentation highlighted the potential clinical utility of the HAV that can be implanted using normal surgical procedures as a readily available, biological alternative for patients at high risk for amputation.

"Compassionate use cases are some of the most challenging cases, often representing second or third-line interventions. We believe the acellular, off-the-shelf availability and resistance to infection highlight the potential for the HAV to be well suited to these difficult revascularization scenarios caused by vascular trauma and advanced PAD where other therapies are not available," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer of Humacyte. "In these compassionate use cases, the HAV performed reliably in the face of infected fields and severe arterial disease, with no infections, and durably, with one patient remaining patent for the duration of the reporting period of 20 months. We believe these results underscore the potential of the HAV to greatly expand opportunities for limb salvage in trauma and urgent vascular reconstruction and we look forward to continuing to follow these patients to fully assess the durability of the HAV."

The presentation is available on [Humacyte.com](https://humacyte.com).

The HAV is currently being evaluated in late-stage clinical trials in vascular trauma repair, arteriovenous access for hemodialysis, and PAD. The HAV is an investigational product candidate and is not currently approved for sale by the FDA or any international regulatory authority. For more information on Humacyte's EAP for HAV, visit <https://humacyte.com/expanded-access-policy/>.

About HAV

Human Acellular Vessels (HAV) are 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. It is 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.

About Humacyte

Humacyte, Inc. (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues and organs 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 HAVs were the first product to receive the FDA's Regenerative Medicine Advanced Therapy (RMAT) expedited review designation and received priority designation for the treatment of vascular trauma by the U.S. Secretary of Defense. For more information, visit 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 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 the registration statement on Form S-1, as amended, filed by Humacyte with the SEC. 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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