Humacyte Presents Positive Long-Term Results of ATEV™ in Treatment of Vascular Trauma in Military Setting from Ukraine Humanitarian Program

- Results presented at the Department of Defense's Military Health System Research Symposium (MHSRS) -

- In real-world military setting the ATEV was observed to have 12-month patency of 87.1% -

- There were zero instances of infection, amputation or death during the long-term follow-up period despite the severity of the wartime injuries treated -

DURHAM, N.C., Aug. 27, 2024 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, yesterday presented positive long-term results from a humanitarian program conducted in Ukraine under which the investigational acellular tissue engineered vessel (ATEV) was used to treat vascular injuries suffered during the ongoing conflict. Long-term follow-up results were presented for the first time and showed high rates of patency (blood flow) and the avoidance of amputation and infection despite the severe nature of the wartime injuries treated. The results were presented at the *Military Health System Research Symposium* (MHSRS), the U.S. Department of Defense's foremost scientific meeting, held in Kissimmee, Florida.

The presentation highlighted the results for 16 extremity patients treated in Ukraine who provided consent for use of their results, a set of data known as the "V017 trial." The primary analyses for the V017 trial were at 30 days of follow up, and as previously reported the rate of success for treatment of patients with the ATEV at this time point was high with primary and secondary patency of 93.8%, zero amputations, and zero cases of infection of the ATEV. Longer-term results for the V017 patients were presented for the first time at the MHSRS meeting, with a mean follow-up duration of 357.9 days. Kaplan-Meier estimates of 12-month primary and secondary patency both were 87.1%. There were no instances of ATEV infections, amputation of affected limbs, or deaths related to ATEV through the end of long-term follow-up. There was one event of ATEV thrombosis after month six. There were no reports of ATEV aneurysm or pseudo-aneurysm. These results were achieved despite the fact that all patients had a high risk of wound infection and were severely injured, with a mean Injury Severity Score (ISS) of 20.1. Patients treated with the ATEV included those injured due to mine blasts, shrapnel and high velocity ballistics.

"We are pleased that the long-term results in a military setting are consistent with the 30-day results previously observed and support the potential durability of the ATEV in vascular trauma patients," said Shamik Parikh, M.D., Chief Medical Officer of Humacyte. "For repair or reconstruction of traumatic vascular injuries when autologous veins are not feasible, the ATEV may offer combat surgical teams an off-the-shelf and universally implantable alternative that has shown extremely low rates of infection, potentially offering durable performance and help with limb salvage."

"We are very grateful for the invaluable support during this difficult time," said Oleksandr Sokolov, M.D., Ph.D., a Ukrainian vascular surgeon who treated patients with the ATEV under the humanitarian program. "The ATEV implantations performed for those wounded by blast injuries have significantly reduced the time of acute ischemia following injury, which has a positive impact on the preservation of lives and limbs. These implantations are quicker due to the absence of the need for vein harvesting for graft preparation and have excellent immunological and infection resistance, making them particularly effective in the context of combat injuries."

The ATEV is an investigational, first-in-class bioengineered human tissue that is designed to be a universally implantable vascular conduit for use in arterial replacement and repair, and for use as hemodialysis access. While harvesting vein from a trauma patient requires critical surgical time, the ATEV is designed to be available off-the-shelf. The ATEV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

About Humacyte

Humacyte, Inc. (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues, advanced tissue constructs, 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 product candidates, a portfolio of ATEVs, are currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous (AV) access for hemodialysis, and peripheral artery disease. A Biologics License Application for the ATEV in the vascular trauma indication is currently under review by the FDA and was granted Priority Review. 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 ATEV for AV access in 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. Humacyte's 6mm ATEV for urgent arterial repair following extremity vascular trauma and for advanced PAD also have received an RMAT designations. The ATEV 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, the outcome of the FDA's review of our BLA seeking approval of the ATEV in the vascular trauma indication; the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials, the anticipated characteristics and performance of our ATEV; our ability to successfully complete preclinical and clinical trials for our ATEVs; the anticipated benefits of the ATEV relative to existing alternatives; the anticipated commercialization of our ATEVs and our ability to

manufacture at commercial scale; the implementation of our business model and strategic plans for our business; and the timing or likelihood of regulatory filings, acceptances, and approvals. 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, 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 described under the header “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, 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. Except as required by law, we have no current intention of updating any of the forward-looking statements in this press release. 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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