Humacyte Submits Biologics License Application (BLA) to U.S. FDA Seeking Approval of Human Acellular Vessel™ (HAV™) for the Treatment of Vascular Traum

– BLA supported by results from Phase 2/3 clinical trial and outcomes of real-world use of the HAV under a humanitarian aid program to treat wartime trauma injuries in Ukraine –

– The HAV had higher rates of patency, and lower rates of amputation and infection, compared to historic synthetic graft benchmarks –

DURHAM, N.C., Dec. 12, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissue at commercial scale, today announced that it has submitted a Biologics License Application (BLA) to U.S. Food and Drug Administration (FDA) seeking approval of the Human Acellular Vessel (HAV) in urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and when autologous vein use is not feasible. The BLA submission is supported by positive results from the V005 Phase 2/3 clinical trial as well as from the treatment of wartime injuries in Ukraine. The HAV was observed to have higher rates of patency (blood flow), and lower rates of amputation and infection, as compared to historic synthetic graft benchmarks.

“Submitting the BLA to the FDA is a pivotal milestone in achieving our goal of providing regenerative human tissues to injured patients, at commercial scale,” said Laura Niklason, MD, PhD, Chief Executive Officer of Humacyte. “I want to thank the patients and medical professionals who participated in our clinical studies, and our Humacyte, team for their tremendous effort and dedication in completing the BLA submission for this first-in-class product candidate.”

The FDA has a 60-day review period to determine whether the BLA is complete and acceptable for filing. Humacyte has requested Priority Review of the application and, if granted, the review should be completed within six months of the filing acceptance date. In May 2023 the FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation for use of the HAV in urgent arterial repair following extremity vascular trauma. In addition, the HAV was assigned a priority designation by the Secretary of Defense under Public Law 115-92, enacted to expedite the FDA’s review of products that are intended to diagnose, treat or prevent serious or life-threatening conditions facing American military personnel, such as traumatic injuries.

About the HAV

The HAV, a bioengineered tissue, is under investigation as an infection-resistant, universally implantable conduit for use in vascular repair. Designed to be ready off-the-shelf, the HAV has the potential to save valuable time for surgeons and to improve outcomes and reduce complications for patients. The HAV can be produced at commercial scale in Humacyte’s existing manufacturing facilities, which are expected to have the capacity to provide thousands of vessels for treating patients in need. The HAV has accumulated more than 1,000 patient-years of experience worldwide in a series of clinical trials in multiple indications, including vascular trauma repair, arteriovenous access for hemodialysis, and peripheral artery disease.

The HAV is an investigational product and has not been approved for sale by the FDA or any other regulatory agency.

Results from V005 Trial and Ukraine Humanitarian Program

Results from the V005 Phase 2/3 clinical trial and from the treatment of wartime injuries in Ukraine were most recently presented in November at the VEITHsymposium®, a major vascular surgery conference in New York City.

The V005 trial is a single-arm study conducted in the U.S. and Israel in patients with arterial injuries resulting from gun shots, workplace injuries, car accidents, or other traumatic events for whom the standard of care, saphenous vein, was not feasible or available for vascular repair. As a single-arm study, the comparators for the HAV results were systematic literature reviews and meta-analysis of studies evaluating synthetic grafts in vascular injury repair. A total of 69 patients were enrolled in the V005 trial, of which 51 had vascular injury of the extremities and comprised the primary evaluation group for the study. The V005 trial met its objectives, and the HAV demonstrated a higher 30-day secondary patency rate of 90.2% for the patients with extremity vascular trauma compared to 78.9% historically reported for synthetic grafts. Primary patency for the HAV was 84.3% for the patients with extremity vascular trauma, although no comparison to synthetic graft primary patency was possible since this measure was not reported in the benchmark publications. The HAV also demonstrated lower amputation rates, with a rate of 9.8% for patients with extremity vascular trauma, compared to 24.3% historically reported for synthetic grafts. Furthermore, the HAV demonstrated lower rates of infection, with a rate of 2.0% for the V005 patients with extremity vascular trauma compared to 8.4% historically reported for synthetic grafts.

The FDA has advised Humacyte to include in the BLA submission patient outcomes from a humanitarian program conducted in Ukraine. The results for the 16 patients from Ukraine with extremity vascular trauma who provided consent for use of their results in the BLA filing are known as the V017 trial. A high success rate for patients in the V017 trial was observed, with a 30-day primary and secondary patency of 93.8%, zero amputations, and zero cases of infection of the HAV. An analysis of an integration of results from the V005 and V017 trials concluded that the HAV demonstrated higher patency with a 30-day secondary patency rate of 91.5% for patients with extremity vascular trauma compared to 78.9% historically reported for synthetic grafts. For the secondary comparison of amputation rates, the HAV demonstrated an improvement, with a rate of 4.5% for integrated V005 and V017 results, compared to 24.3% historically reported for synthetic grafts. For the secondary comparison of infection, the HAV demonstrated an improvement, with a rate of 0.9% for integrated data as compared to 8.4% historically reported for synthetic grafts.

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 HAVs, are currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous (AV) access for hemodialysis, and peripheral artery 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 AV access in hemodialysis was the first product candidate to receive the FDA's RMAT designation and has also received FDA Fast Track designation. Humacyte's 6mm HAV for urgent arterial repair following extremity vascular trauma also has received an RMAT 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.

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; the timing or likelihood of regulatory filings, acceptances and approvals, including the BLA for our V005 clinical trial; 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, 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, 2022 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, each 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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