Humacyte Presents New Immunogenicity Data on Human Acellular Vessels™ (HAVs™)

June 8, 2022

-- Data indicate HAV does not stimulate increase in panel reactive antibodies, an adaptive immune response correlated with increased risk of implant failure --

-- Data presented today in IMPACT session at American Transplant Congress (ATC) 2022 --

DURHAM, N.C., June 08, 2022 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today presented data on more than 500 patients-years of exposure demonstrating the investigational Human Acellular Vessel (HAV) does not stimulate an increase in calculated panel reactive antibodies (cPRA) or show evidence of PRA sensitization (*de novo* cPRA > 20 percent) following HAV implantation. The results are consistent with the absence of HAV rejection in the more than 470 patients implanted with the HAV. The data were presented today at the American Transplant Congress 2022 by Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte.

Humacyte's HAVs are engineered replacement vessels designed to be durable, infection-resistant and off-the-shelf to address long-standing limitations in vessel tissue repair and replacement, including tissue incompatibility and rejection often seen with other biologic implants and synthetic grafts. Prior to tissue and organ transplantation, a routine immunologic measurement of PRA is conducted to estimate the risk of rejection. The formation of *de novo* PRA antibodies after an implant may indicate onset of rejection, and increases in PRA could hinder future organ transplantation.

In a Phase 3 clinical study of patients with end-stage renal disease who received the HAV or a synthetic expanded polytetrafluoroethylene (ePFTE) arteriovenous (AV) graft for hemodialysis access, HAV patients exhibited fewer instances of sensitization than patients with the ePFTE graft, when measured at post-implantation screenings every six months up to 24 months. Additionally, data from more than 377 patients with more than 500 patient-years of exposure from Phase 2 and Phase 3 clinical trials indicate no overall evidence of PRA sensitization following implantation of the HAV.

"We now have data on more than 500 patients-years of exposure strongly suggesting that Humacyte's HAV does not affect panel reactive antibody levels. This, combined with the HAV's ability to repopulate with the patient's own cells to become living tissue, indicate the HAV may help overcome key limitations seen with other biological implants and synthetic grafts, such as tissue infection and rejection," said Dr. Niklason. "These data are also an encouraging validation of patient acceptance of the HAV material."

The HAV is currently being evaluated in late-stage clinical trials in vascular trauma repair, AV access for hemodialysis, and peripheral arterial disease. The HAV is an investigational product candidate and is not currently approved for sale by the FDA or any international regulatory authority.

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 (AV) 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 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.

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 Company's cash runway, 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 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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