Humacyte Announces FDA Communication of Additional Time Required to Complete Review of acellular tissue engineered vessel (ATEV™) BLA for the Treatment of Vascular Trauma

– 2nd quarter conference call to be held Tuesday, August 13th, at 8:30 a.m. ET –

DURHAM, N.C., Aug. 09, 2024 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced that the U.S. Food and Drug Administration (FDA) will require additional time to complete its review of its Biologic License Application (BLA) for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication. The ATEV trauma program BLA was submitted to FDA in December 2023, and the FDA granted a Priority Review in February 2024 and assigned a PDUFA date of August 10, 2024. In a phone call from FDA CBER leadership today, the Company was informed that the FDA required additional time to complete its review.

“We received a call from FDA CBER leadership this afternoon apologizing to us and stating that additional time was required for review.” said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. “FDA leadership noted that Humacyte’s ATEV is a first-in-class product, and that Priority Review had been granted, which allows only a six-month review cycle, as compared to the standard ten-month review cycle for most products. During the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing, including post-marketing and labeling discussions. Based on these interactions, we are confident in the approvability of the ATEV in treating vascular trauma. The FDA leadership expressed an apology for their inability to complete the review by the PDUFA date, and currently we do not yet have a revised action date.”

ATEV is a first-in-class bioengineered human tissue that is designed to be a universally implantable vascular conduit for use in arterial replacement and repair. While harvesting vein from a trauma patient takes valuable surgical time, ATEV is available off the shelf, and does not require further injuring the patient to obtain the needed vascular repair material. Humacyte’s BLA included positive results from the V005 pivotal Phase 2/3 clinical study, as well as real-world evidence from the treatment of wartime injuries in Ukraine under a humanitarian aid program. ATEV was used to repair many types of traumatic injuries including car accidents, gunshot wounds, blast wounds and industrial accidents. It was utilized by vascular and trauma surgeons in Level 1 Trauma centers throughout the U.S. and Israel to repair severe limb-threatening and life-threatening injuries, and in front-line hospitals in Ukraine to treat war injuries. In both the civilian and military clinical studies, ATEV was observed to have high rates of patency, or blood flow, and low rates of amputation and infection.

Conference Call Information

Management will be available during its 2nd quarter 2024 financial report and business update conference call, details ss follows:

Date:	August 13, 2024
Time:	8:30 AM Eastern Time
Conference Call Details:	1-877-704-4453 (U.S. Investors Dial) 1-201-389-0920 (International Investors Dial) 13747913 (Conference ID)
Call me™ Feature:	Click Here
Webcast:	Webcast Link - Click Here

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 with a PDUFA date of August 10, 2024. 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.

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

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 expected PDUFA date for our ATEV in vascular trauma repair; the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials, including our BVP program; the anticipated characteristics and performance of our ATEVs and the BVP; our ability to successfully complete, preclinical and clinical trials for our ATEVs and the BVP; the anticipated benefits of the BVP 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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