Centers for Medicare & Medicaid Services (CMS) Issues ICD-10-PCS Codes for Humacyte's Human Acellular Vessel™ (HAV ™)

– Four unique ICD-10-PCS codes, effective October 1, 2024, for replacement of arteries in the upper and lower extremities using Humacyte's HAV –

– BLA submission under Priority Review by FDA for the treatment of vascular trauma, supported by Phase 2/3 clinical trial results and real-world use treating wartime trauma injuries in Ukraine –

DURHAM, N.C., June 17, 2024 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, Human Acellular Vessels (HAVs) at commercial scale, today announced the issuance of four new ICD-10-PCS codes by the U.S. Centers for Medicare & Medicaid Services (CMS) ICD-10 Coordination and Maintenance (C&M) Committee. These codes, effective for hospital discharges beginning October 1, 2024, cover procedures for replacing arteries in the upper or lower extremities using Humacyte's HAV. Humacyte also announced that, based on guidance from the Food and Drug Administration (FDA), the common (non-brand) name for the HAV will be the "acellular tissue engineered vessel" (ATEV).

The CMS ICD-10 C&M Committee issues ICD-10-PCS codes to facilitate accurate classification and tracking of procedures. The ICD-10-PCS is a classification for procedures performed during inpatient hospital admissions[1]. The codes are widely used by hospitals and insurers to support data collection, payment, and monitoring. Obtaining these codes marks a significant milestone as Humacyte advances toward submission of a New Technology Add-on Payment (NTAP) application to CMS planned for later in 2024. Obtaining an ICD-10-PCS code is necessary to file an NTAP application.

The newly issued codes are:

X2R50WA: Replacement of Right Upper Extremity Artery using Bioengineered Human Acellular Vessel, Open Approach, New Technology Group 10

X2R60WA: Replacement of Left Upper Extremity Artery using Bioengineered Human Acellular Vessel, Open Approach, New Technology Group 10

X2R70WA: Replacement of Right Lower Extremity Artery using Bioengineered Human Acellular Vessel, Open Approach, New Technology Group 10

X2R80WA: Replacement of Left Lower Extremity Artery using Bioengineered Human Acellular Vessel, Open Approach, New Technology Group 10

The ATEV is designed for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and when autologous vein use is not feasible. ATEVs, which are bioengineered human tissues, are under investigation as universally implantable vascular replacements that resist infection and do not require immune suppression. The ATEV is intended to be readily available – "off-the-shelf" – with the potential to save valuable time for surgeons, thereby improving patient outcomes and reducing complications. Humacyte has extensive experience with the ATEV, accumulating over 1,200 patient-years of worldwide use in clinical trials for vascular trauma repair, arteriovenous access for hemodialysis, and peripheral artery disease. The company's manufacturing facilities are capable of producing ATEVs at commercial scale to meet the potential needs of thousands of patients.

The Prescription Drug User Fee Act (PDUFA) date for the FDA's regulatory decision on Humacyte's Biologics License Application (BLA), is August 10, 2024. This is based on a Priority Review which was granted by the FDA. The BLA submission was supported by positive results from the V005 Phase 2/3 clinical trial, and real-world evidence from the treatment of wartime injuries in Ukraine. In these studies, Humacyte's ATEV demonstrated higher patency (blood flow) rates and lower amputation and infection rates as compared to historic synthetic graft benchmarks.

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. 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 RMAT designation and has also received FDA Fast Track designation. Humacyte's 6mm ATEV for urgent arterial repair following extremity vascular trauma also has received an RMAT designation. 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 expected PDUFA date; the statements regarding the initiation, timing, progress, and results of our preclinical and clinical trials; the anticipated characteristics and performance of our ATEVs; our ability to successfully complete, preclinical and clinical trials for our ATEVs; the anticipated benefits of our ATEVs 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; the timing or likelihood of regulatory filings, acceptances and approvals, including the BLA for our V005 clinical trial and the NTAP application to CMS; timing, scope, and rate of reimbursement for our ATEVs; 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, 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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[1] Centers for Medicare & Medicaid Services. (2024). ICD-10-PCS Official Guidelines for Coding and Reporting 2025. Retrieved from https://www.cms.gov/files/document/2025-official-icd-10-pcs-coding-guidelines.pdf

Source: Humacyte, Inc