Humacyte's Human Acellular Vessel™ (HAV™) Receives FDA's Regenerative Medicine Advanced Therapy (RMAT) Designation for Urgent Arterial Repair Following Vascular Trauma

May 4, 2023

HAV granted second RMAT designation by the FDA
RMAT will support Humacyte's lead indication in Vascular Trauma

DURHAM, N.C., May 04, 2023 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, has been recently granted the U.S. Food and Drug Administration's (FDA's) Regenerative Medicine Advanced Therapy (RMAT) designation for its Human Acellular Vessel (HAV) for urgent arterial repair following extremity vascular trauma. The FDA's RMAT designation is for breakthrough therapy of regenerative medicine. The designation allows for more interactions with the FDA and expedited development and review of regenerative medicine products within the U.S., including the potential for priority review process for a Biologics License Application (BLA). This is the second RMAT designation granted by the FDA for Humacyte's HAV, in addition to a previous RMAT granted for arteriovenous (AV) access in hemodialysis.

"We are delighted to receive our second RMAT designation from the Food and Drug Administration," said Dr. Cindy Cao, Chief Regulatory Officer at Humacyte. "The RMAT designation for the HAV in our lead indication of vascular trauma is an important milestone. This designation will further enhance our communication with the FDA and will provide us with a higher likelihood for an expedited review of our planned upcoming BLA filing."

Humacyte's HAV is designed to be a universally implantable vascular conduit for use in vascular repair. Importantly, the HAV has shown a low rate of infection in clinical trials, making it well-suited for use in settings such as vascular trauma where wounds may be contaminated with foreign material. The HAV is designed to be available off-the-shelf and ready whenever surgeons need it, potentially saving valuable time and potentially improving patient outcomes in cases requiring urgent vascular repair, for both civilians and military personnel.

Humacyte is nearing the completion of enrollment in its Phase 2/3 V005 clinical trial of the HAV in the repair of civilian vascular trauma, a study that is being conducted at Level 1 Trauma Centers in the U.S. and Israel. Currently, a total of 66 patients have received the HAV in the V005 trial, including 49 patients comprising the primary endpoint population. Humacyte plans to file a BLA with the FDA later in 2023.

The HAV 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 opportunity, a portfolio of HAVs, is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, 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 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 HAV for urgent arterial repair following extremity vascular trauma also has received 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 and approvals; timing, scope, and rate of reimbursement for our HAVs; the outcome of our ongoing discussions with the FDA concerning the design of our ongoing V005 Phase 2/3 clinical trial, including determination of trial size, and the scope of any approved indication 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 included under the header "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, 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.

Humacyte Investor Contact:
Joyce Allaire
LifeSci Advisors LLC
+1-617-435-6602
jallaire@lifesciadvisors.com
investors@humacyte.com

Humacyte Media Contact:
Rich Luchette
Precision Strategies
+1-202-845-3924
rich@precisionstrategies.com
media@humacyte.com

Source: Humacyte, Inc.