Humacyte Receives Award from the Medical Technology Enterprise Consortium

New Funding to Advance Research on Humacyte’s Investigational Human Acellular Vessel (HAV)

RESEARCH TRIANGLE PARK, N.C. – September 28, 2017 – Humacyte, an innovator in biotechnology and regenerative medicine, has received approximately $650,000 from the Medical Technology Enterprise Consortium (MTEC). This award will help fund the ongoing development and future commercialization of Humacyte’s bioengineered HAV’s application as a conduit for hemodialysis in patients with End-Stage Renal Disease (ESRD). In addition, Humacyte plans to use MTEC funding to further assess the vessel’s stability and potential application towards civilian and combat-related vascular trauma.

MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transaction Agreement (OTA), Agreement No. W81XWH-15-9-0001, with the U.S. Army Medical Research Acquisition Activity (USAMRAA). As a nationally-dispersed consortium with members from industry, academia and the nonprofit sector, the organization’s mission is to assist the U.S. Army Medical Research and Materiel Command (USAMRMC) by providing cutting-edge technologies to transition medical solutions to industry that protect, treat, and optimize Warfighters’ health and performance across the full spectrum of military operations.

“With backing from a collaborative national consortium such as MTEC, we hope to further explore the potential of HUMACYL® for vascular trauma and to test the stability of our vessel under a range of environmental conditions,” said Ted Lithgow, Ph.D., Chief Operating Officer of Humacyte. “We’ve continued to achieve significant milestones for the company, with the recent completion of enrollment of Phase III clinical trials of HUMACYL for patients with ESRD, and our ongoing Phase II clinical trials testing the vessel’s prospects in treating patients with peripheral arterial disease (PAD). Our HAV has the potential to address both military and civilian needs, and help patients suffering from vascular trauma.”

Lester Martinez, MD, MPH, Major General (Retired), U.S. Army, President and Chairman of MTEC Board concurred. “This research embodies the mission of MTEC, to accelerate solutions that restore health for America’s military and veterans. This technology has the potential to make profound differences in wounded warfighters’ lives – to help recover their abilities after severe battlefield injuries. The MTEC membership is proud to be part of an effort to make them whole again,” Martinez shared.

Humacyte recently announced the completion of enrollment of 350 evaluable subjects for its Phase III HUMANITY study of HUMACYL. The company expects 12-month post-implantation patient data from the study to be available in late-2018. With this data, Humacyte plans to file a BLA to seek marketing authorization for HUMACYL. To expedite the review process, Humacyte was granted the Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration’s (FDA) earlier this year.

In addition, the company is seeking regulatory approval for its HAV as a lower extremity arterial bypass vessel in patients with PAD. The company is also continuing its efforts in advancing the development of future pipeline products that may improve treatment outcomes for patients suffering from both vascular and non-vascular diseases.
About Humacyte:

Humacyte, Inc., a privately held company founded by Dr. Laura E. Niklason, M.D., Ph.D., in 2004, is a medical research, discovery and development company with clinical and pre-clinical stage investigational products. Humacyte is primarily focused on developing and commercializing a proprietary novel technology based on human tissue-based products for key applications in regenerative medicine and vascular surgery. The company uses its innovative, proprietary platform technology to engineer human, extracellular matrix-based tissues that can be shaped into tubes, sheets, or particulate conformations, with properties similar to native tissues. These are being developed for potential use in many specific applications, with the goal to significantly improve treatment outcomes for many patients, including those with vascular disease and those requiring hemodialysis. The company’s proprietary technologies are designed to create off-the-shelf products that, once approved, can be utilized in any patient. The company web site is www.humacyte.com.

All statements, other than statements of historical fact, included in this announcement are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “will”, “anticipate”, “expect”, “believe”, “intend” and “should” or the negative of these terms or other comparable terminology. These statements relate to future events or Humacyte’s clinical development programs, reflect management’s current beliefs and expectations and involve known and unknown risks, uncertainties and other factors that may cause Humacyte’s actual results, performance or achievements to be materially different. Except as required by law, Humacyte assumes no obligation to update these forward-looking statements.

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