Science Translational Medicine Publishes Results That Humacyte's "Human Acellular Vessels Recellularize and Evolve into Living Blood Vessels following Human Implantation"

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RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Humacyte, an innovator in biotechnology and regenerative medicine, announced publication in the medical journal *Science Translational Medicine*, of pivotal scientific work demonstrating Humacyte's human acellular vessels (HAVs) repopulate with the patient's own cells to form a living vascular tissue. The published study presents a comprehensive microscopic evaluation of HAV samples retrieved 16 weeks to 4 years after implantation in patients enrolled in the company's Phase II clinical trials providing vascular access for hemodialysis. The results suggest that the HAV may be an innovative advancement as a bioengineered vessel that develops characteristics of a living tissue over time.

Heather Prichard, Ph.D., Humacyte's Chief Operations Officer and former Senior Vice-President of Product Development, is the senior author of the report. *Science Translational Medicine*, a weekly peer-reviewed medical journal, is one of the world's leading medical publications devoted to publishing research and issues of strong interest to the translational medicine community.

Humacyte's HAVs received the FDA's Fast Track Designation in 2014 and the Regenerative Medicine Advanced Therapy (RMAT) designation in 2017. The foundational scientific data published today provides support for the biocompatibility and regenerative nature of the HAV in patients. The HAVs are acellular at the time of implantation into human recipients. However, according to the published analysis of clinical tissue samples, the HAVs became populated with numerous types of the patient's own cells. Over time, the patient's cells transform the HAV into a multi-layered living tissue similar to native blood vessels. The study also showed evidence of ongoing cellular repair of HAV tissues that had been previously injured during cannulation with dialysis needles. These findings may suggest that the recellularized HAV is capable of self-healing.

"As a regenerative medicine product, we're excited to see evidence of functional tissue recellularization in actual patients, which may have the potential to enhance long term efficacy and safety," said Dr. Prichard.

Highlights from the Published Study Include:

- Scanning electron microscopy shows that the HAV is composed of densely-packed and aligned extracellular matrix fibers.
- Following implantation, histological evidence demonstrated recellularization of the HAVs over time, with multiple cell populations from the patient. Cell types identified include smooth muscle and endothelial progenitor cells that mature over time. The histological evidence also suggests that these cells may form distinct tissue layers in the HAV similar to that of native blood vessels. These layers include a surrounding neoadventitial layer containing microcapillaries and progenitor cells, a dense and circumferentially aligned medial smooth muscle layer, and the presence of a potentially functional endothelium on the lumen.
- Regions of the HAV wall that were previously injured or disrupted by needle cannulation during dialysis showed evidence of restoration by host cell populations, which suggests a self-healing potential of recellularized HAVs.
- No evidence of adverse inflammatory or immune reaction to the HAV was observed in the clinical tissue samples.

Humacyte is currently supporting two Phase III trials across 40 sites in the U.S., Europe and Israel. The studies are evaluating the efficacy and safety of the blood vessel as a conduit for hemodialysis in patients with End-Stage Renal Disease (ESRD) requiring renal replacement therapy. To explore additional clinical indications, the company is also conducting a U.S. Phase II clinical trial, investigating use of the HAVs as an arterial bypass vessel in patients with peripheral arterial disease (PAD) and a U.S. Phase II vascular trauma clinical trial, investigating the HAVs in the setting of vascular trauma in patients who require vascular repair.

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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 or sheets, 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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