

Humacyte Announces Issuance of Three Additional U.S. Patents Covering its Proprietary Universally Implantable Bioengineered Human Tissue Platform

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- Patent estate also expanded by the issuance of 23 additional patents in international markets
- Humacyte now owns or licenses 119 patents covering its proprietary platform

DURHAM, N.C., Sept. 20, 2021 (GLOBE NEWSWIRE) -- Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at commercial scale, today announced the issuance of three additional U.S. patents covering its proprietary technology platform. Included in the new patents are additional claims related to the Human Acellular Vessels (HAVs), engineered, off-the-shelf replacement vessels initially being developed for vascular repair, reconstruction and replacement. New U.S. Patents 10,934,532 and 10,947,498, both titled "Tissue-engineered constructs," expand upon existing patents encompassing methods of producing the Company's HAVs and other human tissues, including the scaffolds and methods used to make these product candidates. New U.S. Patent 11,058,534, titled "Tubular prothesis," covers biologic replacements for diseased or damaged anatomical conduits, including the trachea.

For issued U.S. patents, the last patent expires in 2035 and additional U.S. patent applications pending, if issued, would extend coverage into 2040. U.S. Patents 10,934,532 and 10,947,498 are owned directly by Humacyte. U.S. Patent 11,058,534 is jointly owned by Humacyte and Yale University, and Yale has exclusively licensed its rights to Humacyte.

In addition to the U.S. patents, an additional 23 international patents were issued covering the scaffolds used to make Humacyte's vessels, the composition of the vessels, and systems and methods of manufacturing the vessels. Humacyte now owns or licenses a total of 14 U.S. patents and 105 international patents covering its proprietary platform.

"We continue to look for means to expand the protection of our proprietary technology platform through pursuing the patent of new inventions and improvements, whether developed internally or in cooperation with our collaborators," said Laura Niklason, M.D., Ph.D., Founder, President and Chief Executive Officer. "We are pleased with the recent expansion of our patent estate and thank our internal team and key collaborators who have made this exceptional progress possible."

About HAV

Human Acellular Vessels (HAV) are engineered off-the-shelf replacement vessels initially being developed for vascular repair, reconstruction and replacement. HAV is intended to overcome long-standing limitations in vessel tissue repair and replacement – it can be manufactured at commercial scale, it eliminates the need for harvesting a vessel from a patient, and clinical evidence suggests that it is non-immunogenic, infection-resistant, and can become durable living tissue. HAV is currently being evaluated in two Phase 3 trials in AV access and a Phase 2/3 trial for vascular trauma, and has been used in more than 460 patient implantations. It is the first product to receive Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration, and has also received FDA Fast Track designation.

About Humacyte

Humacyte, Inc., (Nasdaq: HUMA) is developing a disruptive biotechnology platform to deliver universally implantable bioengineered human tissues and organs 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 human acellular vessels (HAVs), is currently in late-stage clinical trials targeting multiple vascular applications, including vascular trauma repair, arteriovenous access for hemodialysis, and peripheral arterial disease. Pre-clinical 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 HAVs were the first product to receive the FDA's Regenerative Medicine Advanced Therapy (RMAT) expedited review designation and 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 clinical trials; the anticipated characteristics and performance of our HAVs, our ability to successfully complete clinical trials for our HAVs; the anticipated benefits of our HAVs relative to existing alternatives; the commercialization of our HAVs and our ability to manufacture at commercial scale; the implementation of our business model, strategic plans for our business; the scope of protection we are able to establish and maintain for intellectual property rights covering our HAVs and related technology; the timing or likelihood of regulatory filings and approvals; timing, scope and rate of reimbursement for our HAVs; and our estimated available market opportunity. These forward-looking statements are subject to a number of significant risks and uncertainties that could cause actual results to differ materially fro

economic, business, and/or competitive factors, and those risks and uncertainties included under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Form 8-K filed with the Securities and Exchange Commission on August 30, 2021 and subsequent annual reports, quarterly reports and other filings made with the Securities and Exchange Commission from time to time. 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.

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