

SAVING LIVES

Humacyte perfects technology for growing blood vessels from donor cells.

Durham biotechnology firm Humacyte Inc. has spent more than a decade making a name for itself in regenerative medicine that enables scientists to grow bioengineered blood vessels. Now, the company, which has raised \$480 million over the years, is looking to expand into other human tissues.

The company's lead product, Humacyl, is undergoing clinical trials in patients with peripheral arterial disease and renal failure. Humacyte's goal has been to create long-lasting access to veins or vein replacements for patients on dialysis. Engineered veins would prevent patients from having to use surrogate vessels from other parts of their body.

"Patients on dialysis must have good blood vessels in which needles are placed for the machine which cleans their blood," Chief Operating Officer Heather Prichard says.

About 30 million American adults have chronic kidney disease, according to the National Kidney Foundation. Approximately 475,000 of these patients receive dialysis at least three times per week to replace kidney function.

In 2006, Humacyte was launched with a \$150,000 research loan from the North Carolina Biotechnology Center. Founders were Laura Niklason, a former Duke University professor of anesthesia and biomedical engineering who now teaches at Yale University, and molecular biologist Juliana Blum. The company now has 130 employees. "Our growth is attributed to the fact that the science has come a long way, and the company is beginning to build toward commercial manufacturing," says Prichard, who joined Humacyte in 2008.

Regenerative medicine usually relies on using a patient's own cells to grow organs, and in cases where donor cells are used, rejection is a concern.

Humacyte's processes use donor cells without the threat of rejection, according to Prichard. The vessels are created from donated human muscle cells placed on a small, scaffold-type structure. The tissues grow into a 3D DNA matrix that can be implanted into



Humacyte's lead product, Humacyl, is undergoing clinical trials for patients with renal failure, a longtime goal of the company. It is exploring using donor cells to create blood vessels for those who need them.

the patient. Clinical trials, which involve 450 patients worldwide, suggest the product has the potential to become a part of the body's living tissue.

Humacyte's product has not been approved by the U.S. Food and Drug Administration, but in 2017, it received one of the agency's first Regenerative Medicine Advanced Therapy designations. This means the FDA will help expedite development of the technology for patients who need life-sustaining dialysis.

Plans call for seeking FDA approval for commercial applications next year, Prichard says. "If we are successful, we hope to expand over the next few years to meet market demand."

Last year, the company secured a \$150 million investment from Germany's Fresenius Medical Care, the world's largest dialysis company. That followed several funding rounds, including \$75 million raised in March 2018 from 29 investors. Key funders include the California Institute for Regenerative Medicine, which has provided \$24 million in grants and investments. Also, the U.S. Department of Defense signed a \$3.4 million contract to use Humacyl to treat traumatic vascular injuries.

Recently, Humacyte moved into a building with 80,000 square feet of office, lab and manufacturing space. Plenty of growth opportunities exist, Prichard adds.

"Our technology platform can put the product into many areas," she says. "We can use it for additional places in the body such as the esophagus and the trachea and ultimately use it to create organs." ■

— Teri Saylor is a freelance writer from Raleigh.