



Xcellerex and Humacyte Announce Collaboration to Develop Single-use Manufacturing Technology for Growth of Vascular Grafts for Transplantation

Partnership will enable rapid, cost-effective, production of novel Humacyte vascular grafts for transplantation utilizing Xcellerex's XDR single-use technologies

Marlborough, MA and Research Triangle Park, NC- March 4, 2010 - Humacyte, Inc. and Xcellerex, Inc. have entered into an initial strategic collaboration for Xcellerex to develop a novel manufacturing process that will enable the production of Humacyte's lead regenerative medicine product using Xcellerex's XDR single use bioreactor system in its FlexFactory®. Humacyte's product is a large diameter vascular graft that is based on its innovative and proprietary platform technology for engineering human, extracellular matrix-based tissues that have properties that are similar to native tissues. Humacyte's vascular grafts represent a breakthrough that will first be used for arterio-venous access in patients on hemodialysis and eventually would be used as a replacement of diseased or damaged blood vessels. Xcellerex will provide development expertise and product manufacturing in exchange for manufacturing development fees from Humacyte. Humacyte will utilize the initial grafts produced under this collaboration for preclinical development, and the parties may continue their collaboration for the development of large scale manufacturing of vascular grafts for transplantation for clinical and commercial use. The FlexFactory will enable Humacyte to later scale up its production to meet late stage clinical and worldwide commercial market demands. The technology for cultivation of vascular grafts was developed by Humacyte using small-scale bioreactors that produced one graft at a time. The grafts have successfully completed animal tests, enabling Humacyte to begin scale up for manufacturing of grafts for human clinical trials and eventually commercial production. The collaboration is partially funded by a Small Business Innovation Research grant awarded to the companies by the National Institutes of Health's National Institute of Diabetes and Digestive and Kidney Diseases.

“We are pleased to utilize our unique manufacturing technology and development know-how to enable the rapid development of a potent single-use manufacturing platform for Humacyte. Our technology offers Humacyte a cost-effective and novel manufacturing solution for their full pre-clinical and clinical development needs through to commercial production, using our FlexFactory platform. We are excited to see our novel single use manufacturing technologies applied in such an important application that holds such great promise for significant advances in improving treatment options for patients,” stated Joseph Zakrzewski, Xcellerex's Chairman, President and Chief Executive Officer. “We continue to see the expanding applicability of our technologies to help treat human diseases in not just the over 20 clinical phase drugs manufactured in our technology, but also through such novel applications such as in enabling Humacyte's unique vascular graft technology.”

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The goal of the collaboration is to transform the current small-scale, single graft bioreactor manufacturing process into a robust process able to produce commercial supply of multiple vascular grafts in the more efficient and flexible XDR single use bioreactor system configured in the modular turnkey FlexFactory platform. In the first proof of concept phase of the collaboration, grafts will be produced and subjected to physical and chemical testing to demonstrate equivalence to grafts produced to date using small-scale approaches.

“Our exciting collaboration with Xcellerex will both advance our novel vascular graft for transplantation technologies, but also enable us to move more rapidly into clinical development upon the achievement of key development and preclinical milestones. We are looking forward to working with Xcellerex on this critical novel development and manufacturing program,” said Laura Niklason, Humacyte’s Founder.

The agreement follows collaborative design work by the two companies over a period of several months. Xcellerex is providing in-depth support in single use bioreactor design and FlexFactory configuration to help accelerate Humacyte’s deployment efforts. Humacyte is providing expert cell biology and vascular graft technology and know-how. The FlexFactory line will be assembled, tested, and operated at Xcellerex for protocol development and proof of concept graft production. In subsequent project phases, Xcellerex may also complete engineering and/or GMP manufacturing runs for Humacyte before TransPlanting™ the modular FlexFactory line to Humacyte’s facility for rapid site validation and startup for commercial supply. Financial terms were not disclosed.

About FlexFactory

Xcellerex’s FlexFactory is an innovative, portable manufacturing platform, based on the innovative application of (1) single-use technologies; (2) controlled environmental modules (CEMs); and (3) advanced and proven process automation including electronic batch records. The FlexFactory effectively eliminates clean and steam-in-place and clean room infrastructure, greatly simplifies facility design, reducing manufacturing footprint and capital investment, and creates breakthrough gains in operating efficiency, flexibility and environmental friendliness.

About Humacyte

Humacyte, Inc. is a leader in the development of novel, off-the-shelf extracellular matrix tissue products that will significantly improve treatment outcomes in patients with a variety of illnesses. Humacyte’s platform technology is an innovative and proprietary technology for engineering human, extracellular matrix-based tissues, having properties that are similar to native tissues. Humacyte has already succeeded in developing two different regenerative medicine products, each of which will address major market needs in tissue repair and replacement. In addition, our core technology will enable the development of additional future products. The product pipeline includes a large diameter vascular graft for arterio-venous access for hemodialysis, an injectable therapeutic bulking agent/filler and a small diameter vascular graft for peripheral artery replacement and coronary bypass.

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Humacyte's platform technology, employing unique and proprietary approaches to the generation of tissue replacement products, will enable Humacyte to successfully commercialize replacement tissues for life-saving conditions. These tissue replacements will be available as "off-the shelf" products, and will offer significant advantages over current standards of care for a variety of conditions, in an efficacious and cost-effective manner.

About Xcellerex, Inc.

Xcellerex is revolutionizing the way biomolecules are developed, manufactured and commercialized. The company's unique single-use component technology platform transforms biomanufacturing economics, enabling the development of biotherapeutics and vaccines, and dramatically improving the ability of Xcellerex and its partners to deploy manufacturing capacity. Xcellerex leverages its technology and services platform by: 1) commercializing its FlexFactories (complete, turnkey, modular production trains) and XDR (unique, single use component bioreactor systems); 2) building a portfolio of proprietary biotherapeutics and vaccines through creative alliances and in licensing; and 3) creatively structuring transactions around FlexFactories, XDRs and its pipeline. Learn more at <http://www.xcellerex.com>.

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