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Cellular Dynamics and Northwestern University Take First Steps Toward Rebuilding an Organ Using Manufactured Human Cells

Cutting-edge Study Uses iPSC-derived Cells to Coat Blood Vessels in Kidney Scaffolds

MADISON, Wis., Nov. 18, 2014 (GLOBE NEWSWIRE) -- Cellular Dynamics International (CDI) (Nasdaq:ICEL) today announced the publication¹ of a study in the American Journal of Transplantation describing a key first step in ultimately rebuilding and eventually transplanting organs: recreating a portion of the blood supply infrastructure. Jason Wertheim, M.D., Ph.D., Assistant Professor of Surgery-Organ Transplantation at Northwestern University Feinberg School of Medicine, used CDI's iCell® Endothelial Cells to coat the blood supply system of a kidney scaffold, which is crucial for circulation and nutrient distribution throughout the tissue of any organ. This is a key first step in repairing or regenerating organs for transplant.

Key points:

- Over 120,000 people are currently waiting for an organ transplant, and another person is added to the waiting list every 10 minutes. The number of transplants performed annually falls short of this need by 75%.²
- Patients with end-stage kidney disease account for almost 7% of Medicare costs in the U.S.--costing close to \$35 billion annually—but less than 1% of Medicare patients.³
- Not only is there a shortage of available organs, but often the organs available are not suitable for transplant. Research suggests that these organs can be rehabilitated by replacing the cellular components of the organ with healthy human cells while maintaining the 3D structure of the organ.
- Human cells differentiated from induced pluripotent stem cells (iPSCs) offer a potential solution to the lack of a readily available source of human cells for use in tissue engineering and cell therapy.
- CDI's technology allows iPSCs to be developed for anyone from a standard doctor's office blood draw and differentiated into potentially any cell in the body at the quality, quantity and purity necessary for a regenerative therapy.
- The published study describes the recellularization of a rat kidney vasculature extracellular matrix using iCell Endothelial Cells derived from human iPSCs.
- The first step in the study optimized the process of removing cells from the rat kidney, leaving a 3D scaffold of the organ's structure. Next, the authors infused the scaffold with human renal cells to form tubule-like structures, and human iCell Endothelial Cells to coat the blood vessels lining the kidney.
- The authors found that the method of cell removal was important to maintaining key proteins used by the blood vessel matrix. They fluorescently labeled the endothelial cells and saw that indeed the infused cells were incorporated into the blood vessel matrix throughout the kidney scaffold.
- This research demonstrates the potential to generate the vasculature of a complex 3D organ, a key first step in supplying the tissue with required nutrients.
- Given that CDI's technology allows patient-specific cells to be developed potentially into any cell in the body, this work holds promise for the future bioengineering of other complex organ tissues and for reducing the chance of rejection, a key concern in any transplant.

Quotes:

Bob Palay, chief executive officer of CDI, said, "Over 120,000 people are waiting for organ transplants. Unfortunately many are not able to receive lifesaving organs in time. We are delighted to have manufactured the iCell Endothelial Cells that Dr. Wertheim used in this breakthrough study. He was able to use CDI's manufactured human endothelial cells to demonstrate the first step toward rebuilding the blood supply system of a kidney. His work is important in uncovering how manufactured human cells can be utilized to repair and regenerate damaged organs. We look forward to continuing to work with Dr. Wertheim's and other investigators' laboratories as they push forward their efforts to repair and regenerate organs."

Dr. Wertheim said, "Our study establishes an effective method to generate a kidney scaffold that contains important proteins that may direct cell growth in three-dimensions and is a first step toward developing the vasculature of a replacement organ. We show that this scaffold supports cell growth and proliferation, to generate structures reminiscent of tubules and blood vessel-like structures lined by cells made by induced pluripotent stem cell technology." Dr. Wertheim does not hold any financial conflict of interest with CDI or the content of this press release.

¹American Journal of Transplantation, <http://onlinelibrary.wiley.com/doi/10.1111/ajt.12999/abstract>

²US Dept of Health & Human Services, <http://optn.transplant.hrsa.gov/learn/about-transplantation/how-organ-allocation-works/>

³American Society of Nephrology, <https://www.asn-online.org/policy/fact-sheets.aspx>

About Cellular Dynamics International, Inc.

Cellular Dynamics International, Inc. (CDI) is a leading developer and manufacturer of fully functioning human cells in industrial quantities to precise specifications. CDI's proprietary iCell Operating System (iCell® O/S) includes true human cells in multiple cell types (iCell products), human induced pluripotent stem cells (iPSCs) and custom iPSCs and iCell products (MyCell® Products). CDI's iCell O/S products provide standardized, easy-to-use, cost-effective access to the human cell, the smallest fully functioning operating unit of human biology. Customers use our iCell O/S products, among other purposes, for drug discovery and screening; to test the safety and efficacy of their small molecule and biologic drug candidates; for stem cell banking; and in the research and development of cellular therapeutics. CDI was founded in 2004 by Dr. James Thomson, a pioneer in human pluripotent stem cell research at the University of Wisconsin-Madison. CDI's facilities are located in Madison, Wisconsin, with a second facility in Novato, California. See www.cellulardynamics.com.

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Forward-looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Cellular Dynamics International, Inc., including statements regarding the impact or significance of the published research using our products described in this press release, the potential of our products demonstrated by this research, and the potential differentiation of iPSCs into any cell in the human body, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "believe," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our product development efforts, actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements. Cellular Dynamics undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see Cellular Dynamics' Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on March 11, 2014, which risks are incorporated herein by reference, and as may be described from time to time in Cellular Dynamics' subsequent SEC filings.

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