Cellular Dynamics Manufactures cGMP HLA "Superdonor" Stem Cell Lines to Enable Cell Therapy With Genetic

February 09, 2015 08:00ET| **Source:** Cellular Dynamics International, Inc.

MADISON, Wis., Feb. 9, 2015 (GLOBE NEWSWIRE) -- Cellular Dynamics International, Inc. (CDI) (Nasdaq:[ICEL](http://globenewswire.com/News/Listing?symbol=ICEL&exchange=2)) today announced that it has manufactured, under current Good Manufacturing Practices (cGMP), stem cell lines from two HLA "superdonors." HLA superdonors are individuals whose genetic HLA (human leukocyte antigens, or HLA) profiles make their cells or tissues more compatible for donation to unrelated patients—a concern that arises with organ or tissue transplantation and potential rejection. As the first announced HLA superdonor master cell bank in the world, and the first produced under cGMP, these cell lines will enable a new area of cell therapy research using HLA matching.

Key points:

* CDI now has two HLA superdonor cell lines, providing a partial HLA match to 19 percent of the U.S. population. The Company plans to continue to expand this master stem cell bank with the collection of additional donor cell lines to cover 95 percent of the U.S. population.
* CDI manufactured the HLA superdonor cell lines from blood samples collected from eligible anonymous donors.  These donors consented to broad commercial use of their donated samples, including research and therapeutic applications. The induced pluripotent stem cell (iPSC) lines made from the donor samples are pluripotent, meaning they can be used to produce virtually any cell type in the human body.
* cGMP conditions are required for the use of cells as a cellular therapy. CDI's cGMP HLA superdonor stem cell lines can be used to manufacture tissue cells for potential cell therapy and organ rehabilitation. CDI currently manufactures human cells derived from iPSCs for more than 12 cell types, including brain, heart, liver, and blood vessel cells, under the iCell® brand name.
* CDI's HLA superdonor cell lines will be available, including use for developing cellular therapies within a clinical setting.

Scientific details:

* The HLA superdonor iPSC line was manufactured using CDI's proprietary episomal reprogramming method. This non-integrating methodology is expected to alleviate major safety concerns over the potential use of iPSC-derived tissue cells in cellular therapies and removes a significant barrier for applying the technology in a clinical setting.
* HLAs allow the immune system to distinguish "self" from "non-self" and are a key part of the match made in tissue and organ transplants.
* Current alternatives for tissue or organ transplants include autologous, allogeneic, and partial match, or HLA superdonor options:
  + CDI's technology enables the autologous, personalized medicine approach, and the Company already has a contract with the National Eye Institute whereby Retinal Pigment Epithelial (RPE) cells will be manufactured from individuals suffering from dry age-related macular degeneration (AMD).
  + Allogeneic transplants have low or poor matching qualities between the donated tissue and the patient, thus resulting, too often, in rejection.
  + The HLA superdonor approach presents a partial HLA match that has been shown to be beneficial in organ transplants.  With CDI's proprietary process for mass producing human cells, in this case the HLA superdonor iPSCs and differentiated cell types made from these iPSCs, the Company has the ability to be the primary driver in this business.

Quotes:

Bob Palay, CDI chairman and chief executive officer, said, "As we age, our cells can become damaged. Cell therapy offers the promise for the repair and replacement of this damage and for the regeneration of healthy tissue. CDI is delighted to have produced two HLA superdonor iPSC lines that match 19% of the U.S. population, and over time we plan to build a bank that will match 95% of the U.S. population. We expect this bank to prove to be an excellent resource for CDI and others to develop HLA matched cell therapies."

Emile Nuwaysir, CDI chief operating officer, said, "There's great interest for HLA superdonor iPSCs as the starting material for the development of cellular therapies. This strategy combines the best elements—the cost benefits of the allogeneic approach with the immune matching of the autologous approach, to provide a new option for cell therapy development. With the first cGMP HLA superdonor cell bank in the world now available, we look forward to seeing this field develop."

**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](http://globenewswire.com/Tracker?data=90ylXkMBYeVGoWwjEeOYWwOnbfUeN3-j4O87n9oxzKczXjrCtUhGrwEvuLqlwOmhSLF6qTFsdQqHjPWUl-lttuhZ7qxnBAIunFtjokkhGo0%3D).  
  
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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 benefits and utility our HLA superdonor stem cell lines and tissue cells made from those stem cell lines, 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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