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Cellular Dynamics Announces the Production of Human iPSC Lines Under cGMP Conditions

cGMP iPSC Lines Enable the Possible Use of iPSC-derived Human Cells within a Clinical Setting

MADISON, WIS., January 17, 2013 –Cellular Dynamics International, Inc. (CDI), a leading commercial producer of human induced pluripotent stem cell (iPSC) lines and tissue cells for drug discovery and safety, today announced that it is producing human iPSC master cell banks from five individual donors under current Good Manufacturing Practices (cGMPs). Manufacturing human iPSCs and ultimately human cells under cGMPs enables the possible use of iPSC-derived human cells within a clinical setting.

"Reaching this manufacturing milestone is a critical step toward the development and manufacture of human cell-based therapies based on iPSC technology," said Robert Palay, CDI CEO. "We believe that CDI's tight quality controls coupled with our ability to manufacture billions of cells per day will enable iPSC technology to be incorporated in cell therapeutic applications, which will need a steady and large source of high quality human cells."

CDI's iPSC reprogramming and differentiation processes are highly controlled with strong quality management systems, robust operating procedures, and well-defined raw materials. CDI produces iPSCs using a proprietary episomal reprogramming process established by CDI founder James Thomson, Ph.D. and Junying Yu, Ph.D. at the University of Wisconsin and by Amanda Mack at CDI, whereby iPSCs can be created from somatic cells without the integration of foreign DNA into the genome, and with the use of only fully defined, animal-free, and feeder-free conditions. A discussion of CDI's cGMP manufacturing process will occur at the [Scale-Up and Manufacturing of Cell-Based Therapies II Conference](#) on Jan. 21-23 in San Diego.

CDI plans to create cGMP human iPSC master cell banks from blood samples drawn from five individuals who have been previous blood or tissue donors. The company is selecting the individuals based on the donor's HLA (human leukocyte antigen) profile, choosing those donors whose HLA profile makes their cells or tissues most amenable for donation to unrelated recipients. HLA matching is important in tissue and organ transplants, as matched cells and tissues are much less likely to be rejected by a recipient's body.

"We're strategically selecting our first five donors based on their HLAs to create the largest possible pool of potential recipients in the general population," said Emile Nuwaysir, chief operating officer of CDI. "We expect to expand this coverage in the future by selecting additional donors to create master cell banks with a beneficial genetic match to the majority of the North American population. Many scientists believe that iPSC-based cell therapies that employ this HLA matching strategy should result in reduced use of immunosuppressive drugs and be better tolerated by patients. We are excited to take a leading role in this very important area as iPS cells begin to make their migration into cellular therapeutics."

About Cellular Dynamics International, Inc.

Cellular Dynamics International, Inc. (CDI) is a leading developer of stem cell technologies for in vitro drug development, in vivo cellular therapeutics, and stem cell banking. CDI harnesses its unique manufacturing technology to produce differentiated tissue cells in industrial quality, quantity and purity from any individual's stem cell line created from a standard blood draw. 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. See www.cellulardynamics.com.