

## FUJIFILM CELLULAR DYNAMICS BEGINS OPERATIONS FOR ADVANCED CELL THERAPIES AT ITS NEW FACILITY

MADISON, Wis., March 2, 2019 — FUJIFILM Cellular Dynamics, Inc. (FCDI), a leading global developer and manufacturer of human induced pluripotent stem cells (iPSC) technologies, will begin operation of its new cGMP-compliant<sup>\*1</sup> iPSC production facility on March 4. The new facility called “Innovation Facility for Advanced Cell Therapy” (i-FACT), will house development, and manufacture of iPSCs for therapeutic applications. The i-FACT will enable FCDI to accelerate the development of its own pipeline of regenerative medicine therapies using iPSCs, and it will also serve as a Contract Development and Manufacturing Organization (CDMO) of iPSCs and iPSC-derived differentiated cells.

The 32,000 square feet facility design features four development laboratories and three cGMP suites for in-house therapeutic development and for collaboration with other companies. The facility is designed to enable each suite to manufacture a different product to offer scale-up<sup>\*2</sup> and scale-out<sup>\*3</sup> biomanufacturing ability; this approach facilitates FCDI in manufacturing various batch sizes. A quality department has been built up at the front lines of the manufacturing to ensure the accuracy and quality of iPSC therapeutic products developed and manufactured at i-FACT. The facility serves production of high-quality iPS Cells in high efficiency, using FCDI’s world-leading iPS Cells reprogramming and differentiation technologies and FUJIFILM Corporation’s advanced technologies such as engineering and image analysis.

“Over the years, FCDI has provided millions of high quality human iPSCs to our partners engaged in life science research,” said Takeshi Yamamoto, CEO, FUJIFILM Cellular Dynamics Inc., “We are excited to begin operations at i-FACT as it signals an expansion of our business into cell therapies. At FCDI, we are fully committed to leveraging the power of human-iPSCs to transform scientific research and revolutionize healthcare.”

Cell therapies can provide a comprehensive approach to address unmet medical needs with the goal to improve how patients are treated. Among them iPSCs have the capacity to revolutionize the healthcare field by their incredible capacity to self-renew and have already shown utility for life science research purposes. FCDI’s internal pipeline focuses on developing off-the-shelf allogeneic cell therapy candidates in the areas of ocular diseases including age-related macular degeneration and retinitis pigmentosa, heart failure, immuno-oncology and Parkinson’s disease. In the field of oncology, Fujifilm has partnered with a major U.S. venture capital, Versant, and its new company, Century Therapeutics, with the goal of developing next-generation immunotherapies for cancer using allogeneic iPS cell-derived CAR-T cells.

In addition to developing cell therapeutic candidates, FCDI will also continue to manufacture and develop its discovery research products including iCell and MyCell products which are used worldwide to support drug discovery research, safety and toxicity testing.

i-FACT is the Fujifilm Group's second production site of regenerative medicine therapeutic candidates. Of note, Japan Tissue Engineering Co., Ltd. (J-TEC), part of Fujifilm Group operates a manufacturing facility which developed and marketed Japan's first regenerative medicine product.

Fujifilm is committed to contributing to the establishment of the regenerative medicine industry by tapping into the technologies and combined know-how of Fujifilm and its Group companies including J-TEC, FUJIFILM Wako Pure Chemical Corporation and FUJIFILM Irvine Scientific, Inc.

※1 "cGMP" stands for "current Good Manufacturing Practice." It refers to the most recent rules and regulations for manufacturing and quality control of pharmaceuticals and quasi-drugs as determined by the US Food and Drug Administration (FDA).

※2 "Scale up" refers to making a small-scale model to larger-scale commercial equipment while replicating the effect.

※3 "Scale out" refers to increasing the number of manufacturing facilities to increase production capacity.

### [ Overview of the new production facility ]

1. Name Innovation Facility for Advanced Cell Therapy
2. Location Madison, Wisconsin U.S.A.
3. Investment amount Approx. 2.5 billion yen (approx. \$21 Million)
4. Production items Therapeutic iPSCs and iPSC-derived differentiated cells
5. Main equipment Large-scale and small-scale culturing equipment, evaluation system for cell quality, etc.
6. Total floor area Approx. 3,000 m<sup>2</sup> (approx. 32,300 square feet)
7. Operation commencement date March 4, 2020

### [ Exterior view of the new production facility "i-FACT" ]



## **About Fujifilm**

FUJIFILM Cellular Dynamics, Inc. (FCDI) is a leading developer and manufacturer of human induced pluripotent stem cells (iPSCs) utilized in drug discovery and cell therapies. The pre-clinical stage company is using its expertise in iPSC technologies to develop a robust pipeline of cell therapeutics candidates. For its partners, FCDI utilizes its iPSC platform to advance the progress of therapeutic candidates in the clinic and provides contract development and manufacturing (CDMO) services. In addition to cell therapy, FCDI also offers life science research tools including the company's inventoried iCell® products are available in almost any cell type and they are sourced from multiple cell lines which can be applied for target identification as well as toxicity testing. The company also offers custom cell services and cell banking. FCDI's goal is to leverage the vast utility of iPSCs to advance human health and improve the quality of life for patients around the world. For more information, please visit: [www.FujifilmCDI.com](http://www.FujifilmCDI.com)

FUJIFILM Corporation, Tokyo, Japan is one of the major operating companies of FUJIFILM Holdings Corporation. The company brings cutting edge solutions to a broad range of global industries by leveraging its depth of knowledge and fundamental technologies developed in its relentless pursuit of innovation. Its proprietary core technologies contribute to the various fields including healthcare, graphic systems, highly functional materials, optical devices, digital imaging and document products. These products and services are based on its extensive portfolio of chemical, mechanical, optical, electronic and imaging technologies. For the year ended March 31, 2019, the company had global revenues of \$22 billion, at an exchange rate of 111 yen to the dollar. Fujifilm is committed to responsible environmental stewardship and good corporate citizenship. For more information, please visit: [www.fujifilmholdings.com](http://www.fujifilmholdings.com).

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