

News Release

HITACHI
Inspire the Next

FOR IMMEDIATE RELEASE

Hitachi launches Automated Cell Mass Culture Equipment for iPS cells to spread Regenerative Medicine First commercial equipment was installed to the Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy



Automated Cell Mass Culture Equipment for iPS cells

Tokyo, March 11, 2019 --- Hitachi, Ltd. announced today that Hitachi has launched the automated cell mass culture equipment*¹ for the first time in Japan*² which is able to manufacture commercial iPS cells for regenerative medicine. The first equipment was installed to the Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy (SMaRT) of Sumitomo Dainippon Pharma Co., Ltd. on March 8, 2019. This equipment is the first equipment in Japan which has the necessary functions to comply with the Japanese regulation, GCTP*³ (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice) and can be used to culture automatically a mass of iPS cells for clinical use. Adopting the closed flow channel for connection with the culture vessels and the medium bottles, the equipment is capable of cell seeding, culturing, and monitoring in sterile environment and offers stable supply of high quality cells.

The iPS cells, called induced pluripotent stem cells, are able to differentiate into many types of tissues and organs, so they are expected to repair wounded cells as regenerative medicine. After an investigator-led clinical research of an ocular disease using the iPS cells was conducted for the first time in Japan in 2014, clinical researches of advanced cardiac failure and spinal cord injuries using iPS cells are proceeding. Moreover, the investigator-led clinical trial of Parkinson's disease*⁴ using iPS cells was started for the first time in Japan in 2018. On the other hand, iPS cell culturing is mainly performed on manual operation by skilled workers and the cell mass culture technology is needed so that regenerative medicine using human iPS cells will be popular.

Sumitomo Dainippon Pharma has been focusing on regenerative medicine and is conducting the researches using iPS cells in order to overcome incurable diseases such as eye disease and neurologic disease cooperating with academia and venture companies. Especially Sumitomo Dainippon Pharma addresses practical uses of allogeneic iPS cell^{*5}-derived dopaminergic neural progenitor cells^{*6} for treating Parkinsons disease caused by dopamine neuron loss and neurodegeneration with Center for iPS Cell Research and Application, Kyoto University (CiRA).

Hitachi and Sumitomo Dainippon Pharma have collaborated to develop the automated cell culture technology since 2015, and Hitachi installed the automated cell mass culture equipment for research use to Sumitomo Dainippon Pharma on June 2017. Moreover, Hitachi has repeatedly continued discussions with Sumitomo Dainippon Pharma about commercialization of the equipment and consequently launched the automated cell mass culture equipment for iPS cells, which has the necessary functions to comply with GCTP for the first time in Japan. The equipment has not only the closed flow channel but also the functions for management of manufacturing and quality for regenerative medicine products, for example "Design for Validation (including CSV^{*7})", "Audit Trail Function", "Decontamination Resistance", and "Maintaining Cleanliness of Installation environment". In addition, another equipment will be installed to SMaRT by the end of March 2019. Providing these equipments, Hitachi assist Sumitomo Dainippon Pharma to establish manufacturing system of regenerative medicine products for commercial use.

Furthermore, Hitachi and Sumitomo Dainippon Pharma are jointly developing the base technology and evaluation methods within the framework of the "Development of iPS cell-derived neural cell product to treat Parkinsons disease", awarded by Japan Agency of Medical Research and Development (AMED).

Hitachi will conduct proposal activities of the equipment to pharmaceutical companies and start-up companies that develop and manufacture regenerative medicine products using iPS cells. Furthermore, Hitachi group will contribute to spread regenerative medicine providing the total solution for example cell manufacturing facility, related equipment and IT system, contract development and manufacturing and maintenance services.

In addition, Hitachi group will exhibit at the 18th congress of the Japanese Society for Regenerative Medicine held at the Kobe International Exhibition Hall (Kobe, Japan) from March 21 to March 23, 2019.



Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy (SMaRT)

Note:

*1 Automated cell mass culture equipment is not a medical device specified by the Pharmaceutical and Medical Device Act (PMD Act) in Japan

*2 Investigated by Hitachi as of March 11, 2019

*3 GCTP (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice): ordinance on standards for manufacturing control and quality control of regenerative medicine products

*4 Parkinsons disease: a neurodegenerative disorder caused by dopamine neuron loss and neurodegeneration that affects body movements

*5 Allogeneic iPS cells: cells arent from patients own (autologous) cultured cells but from someone elses (allogeneic) cultured cells

*6 Dopaminergic neural progenitor cells: progenitor cells can be differentiated to dopaminergic neurons which release dopamine as a neurotransmitter

*7 CSV (Computerized System Validation) is the process of providing documented evidence that a computer system for developing medicine meets a set of defined system requirements from development stage to ensure accuracy, reliability, consistent intended performance.

Inquiries

Analytical Systems Division, Healthcare business unit, Hitachi, Ltd.

Email: hc.rm.ro@hitachi.com

About Hitachi, Ltd.

Hitachi, Ltd. (TSE: 6501), headquartered in Tokyo, Japan, delivers innovations that answer society's challenges, combining its operational technology, information technology, and products/systems. The company's consolidated revenues for fiscal 2017 (ended March 31, 2018) totaled 9,368.6 billion yen (\$88.4 billion). The Hitachi Group is an innovation partner for the IoT era, and it has approximately 307,000 employees worldwide. Through collaborative creation with customers, Hitachi is deploying Social Innovation Business using digital technologies in a broad range of sectors, including Power/Energy, Industry/Distribution/Water, Urban Development, and Finance/Social Infrastructure/Healthcare. For more information on Hitachi, please visit the companys website at <http://www.hitachi.com>.

###

Information contained in this news release is current as of the date of the press announcement, but may be subject to change without prior notice.
