

News Release

FOR IMMEDIATE RELEASE

Hitachi is selected by Sumitomo Dainippon Pharma for Automated Cell Mass Culture Equipment for Regenerative Medicine using Human iPS Cells

Research equipment for the manufacturing cells used in Parkinson's disease treatment

Tokyo April 10, 2017 -- Hitachi, Ltd. announced today that Hitachi has received an order for automated cell mass culture equipment for regenerative medicine using human iPS cells from Sumitomo Dainippon Pharma Co., Ltd.

This equipment adopts a closed flow channel^{*1} with excellent sterility and reduces pathogen and microbial contamination from the external environment. Sumitomo Dainippon Pharma addresses practical uses of allogeneic iPS cell^{*2}-derived dopaminergic neural progenitor cells^{*3} with which treat Parkinson's disease^{*4} caused by dopamine neuron loss and neurodegeneration with Center for iPS Cell Research and Application, Kyoto University (CiRA). Hitachi contributes to the research of Sumitomo Dainippon Pharma to make dopaminergic neural progenitor cells practical use by offering this equipment. Furthermore, Hitachi and Sumitomo Dainippon Pharma have been a joint research within the framework of the "Project Focused on Developing Key Evaluation Technology: Evaluation for Industrialization in the Field of Regenerative Medicine", awarded by Japan Agency of Medical Research and Development (AMED) with a view to evaluating validity of processing methods adjusted for practical use of the automatic cell culture equipment which aims at the clinical treatment of patients with Parkinson's disease by using human iPS cells.

The iPS cells, called pluripotent stem cells, are able to develop into many types of tissues and organs, so they are expected to repair wounded cells as the regenerative medicine. An investigator-led clinical trial of an ocular disease using the iPS cells was conducted for the first time in Japan in 2014. Moreover, promoting commercialization of the regenerative medicine was enforced in November 2014. Therefore, the market size of the regenerative medicine in Japan was predicted to expand, and the market size including the regenerative medicine-related industries will be about 190 billion yen^{*5} in 2020 and be about 3,800 billion yen^{*5} in 2050. On the other hand, resolutions of many technical challenges are needed so that regenerative medicine using human iPS cells will be popular. Especially, automation of manufacturing processes done by mostly

hand and a supply of high quality cells at reasonable price are essential.

Sumitomo Dainippon Pharma has been undertaken the research in the field of regenerative medicine since the 1980s, and is conducting the research using the iPS cells in order to overcome incurable diseases such as Parkinson's disease, age-related macular degeneration (AMD)^{*6}, retinitis pigmentosa^{*7} and spinal cord injury in cooperation with venture companies, universities and research institutes at present.

Hitachi has delivered not only pharmaceutical plants but also regenerative medicine plants including cell processing facilities, biosafety cabinets for manufacturing and manufacturing execution system (MES) to pharmaceuticals.

Moreover, Hitachi has provided clinical blood analyzers and sample preparation system for medical institutions, and develop inspection systems in the process of manufacturing medicine for the pharmaceuticals. Furthermore, Hitachi has been developing the automated cell culture technology through participation in national projects^{*8} and The technology that are developed at the project is applied to this equipment.

The automated cell culture equipment at this order consists of single-use consumables such as bottles, tubes and cell culture dishes. It cultures and differentiates the iPS cells efficiently because it can manufacture large amounts of the cells automatically and observe the cells under the closed sterile environment.

Hitachi will meet various kinds of needs from the customers in the regenerative medicine market, and promotes the development and the sale from now on, and then contributes to the progress of healthcare.

Note:

*1 a closed flow channel: replace cell culture medium in the cell culture dishes under the closed sterile environment in order to avoid pathogen and microbial contamination from the external environment

*2 allogeneic iPS cells: cells aren't from patient's own (autologous) cultured cells but from someone else's (allogeneic) cultured cells

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

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

*5 Source: Ministry of Economy, Trade and Industry “Final Report Compiled by the Study Group on Commercialization and Industrialization of Regenerative Medicine” in 2013

*6 age-related macular degeneration (AMD): macular degeneration with aging weakens eyesight

*7 retinitis pigmentosa: degeneration of rod photoreceptor cells in a retina weakens eyesight

*8 New Energy and Industrial Technology Development Organization (NEDO), “Basic Technologies Research Promotion Project”, Cabinet Office, Government of Japan, “Funding Program for World-Leading Innovative R&D on Science and Technology(FIRST)”, Ministry of Education, Culture, Sports, Science and Technology, “Creation of Innovation Centers for Advanced Interdisciplinary Research Areas Program”

About Hitachi, Ltd.

Hitachi, Ltd. (TSE: 6501), headquartered in Tokyo, Japan, delivers innovations that answer society’s challenges. The company’s consolidated revenues for fiscal 2015 (ended March 31, 2016) totaled 10,034.3 billion yen (\$88.8 billion). The Hitachi Group is a global leader in the Social Innovation Business, and it has approximately 335,000 employees worldwide. Through collaborative creation, Hitachi is providing solutions to customers in a broad range of sectors, including Power / Energy, Industry / Distribution / Water, Urban Development, and Finance / Government & Public / Healthcare. For more information on Hitachi, please visit the company's website at <http://www.hitachi.com>.

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