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Center for iPS Cell Research and Application, Kyoto University

Sumitomo Chemical Co., Ltd.

Sumitomo Dainippon Pharma Co., Ltd.

**Kyoto University's Center for iPS Cell Research and Application,
Sumitomo Chemical, and Sumitomo Dainippon Pharma Commence Joint Research on
Producing Higher-Quality iPS Cells for Clinical Use**

Kyoto University's Center for iPS Cell Research and Application (CiRA), Sumitomo Chemical Co., Ltd. (Sumitomo Chemical), and Sumitomo Dainippon Pharma Co., Ltd. (Sumitomo Dainippon Pharma) today announced that they have started joint research on producing higher-quality iPS cells for clinical use.

Since fiscal 2013, CiRA has been advancing the project "iPS Cell Stock for Regenerative Medicine*", in which, at its cell processing center (CPC) for clinical-grade cell production "Facility for iPS Cell Therapy (FiT)", CiRA has been producing a stock of iPS cells used for regenerative medicine. Meanwhile, for the first clinical trial in Japan of the iPS cell-based treatment for Parkinson's disease, Sumitomo Dainippon Pharma has established a master cell bank by expanding a stock of iPS cells, and using iPS cells from the master cell bank, CiRA has been producing dopaminergic progenitors, the transplanted cells in this treatment, at FiT. In this way, CiRA and Sumitomo Dainippon Pharma have built a steady track record of production of cell products for clinical use.

For promoting the use of iPS cell-based cell therapies, it is essential to produce high-quality and uniform iPS cells on a large scale stably. In stringently controlled CPCs, however, it is not necessarily easy to reproduce technology developed in laboratories. An important issue, therefore, is to develop and validate technologies in CPCs, which are applicable to commercial production. To resolve this challenge, Sumitomo Chemical and Sumitomo Dainippon Pharma, appreciating the high CPC controlling capability of FiT, which has succeeded in producing Japan's first iPS cell stock and iPS cell-derived cells for the clinical trial, have launched this joint research with CiRA.

In this joint research, CiRA, Sumitomo Chemical and Sumitomo Dainippon Pharma will work on the modification of existing production processes and explore new technologies to improve the quality of iPS cells for clinical use by bringing in CiRA's iPS cell production and quality control technologies at FiT, Sumitomo Dainippon Pharma's commercial production and quality control technologies for cell products for regenerative medicine, and Sumitomo Chemical's stem cell-

related technologies. Through these initiatives, they will work to establish clinical-grade iPS cell production technologies that can be applied for more efficient and stable commercial production, thereby promoting the use of high-quality iPS cells for clinical use in the medical industry.

Professor Shinya Yamanaka, Director of CiRA, comments, “To deliver the benefits of iPS cell technology to patients, it is essential to establish reliable cell culture technologies that will be a base for iPS cell technology. By sharing with Sumitomo Chemical and Sumitomo Dainippon Pharma our experience in cell production and quality control at FiT, which produced iPS cells for the academia-originated clinical trial, I expect further improvements will be achieved in the quality of iPS cells for clinical use.”

* iPS Cell Stock for Regenerative Medicine

In this project, CiRA prepares and stores iPS cell lines for clinical application. Each line is derived from healthy HLA (human leukocyte antigen) homozygous donors, who have cell types that are unlikely to cause severe immune reaction for many recipients.

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