

March 1, 2018

Sumitomo Dainippon Pharma Co., Ltd.

<u>Sumitomo Dainippon Pharma Completes Manufacturing Plant for Regenerative Medicine & Cell Therapy</u>

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Masayo Tada) announced today the completion of the <u>Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy</u> ("SMaRT"; hereinafter, the "Plant") at its Central Research Laboratories (Suita City, Osaka).

Comprising two aboveground levels with a total floor area of 2,915m², the Plant is the world's first facility dedicated to the commercial manufacture of regenerative medicine and cell therapy products derived from allogeneic iPS cells. Together with partners from the industrial and academic sectors, Sumitomo Dainippon Pharma is currently engaged in the regenerative medicine and cell therapy business using allogeneic iPS cells for the treatment of age-related macular degeneration, Parkinson's disease, retinitis pigmentosa, spinal cord injury, and other ailments. The function of the Plant is the manufacture of investigational agents and early-stage commercial production.

The three points below outline the basic concept of the Plant.

- Compliance with the latest regulations for quality assurance, including GCTP (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice) and cGMP (current Good Manufacturing Practice)
- 2. Establishment of production lines with all manufacturing processes conducted basically within a closed system
- 3. Each production zone can work independently by the individual air-conditioning system in accordance with each production schedule flexibly

Operations at the Plant are scheduled to start in March 2018. The expected total construction cost is approximately 3.6 billion yen.

With the opening of the Plant, Sumitomo Dainippon Pharma aims to provide innovative regenerative medicine and cell therapy products derived from iPS cells to patients the world over by further enhancing its technology and knowhow for manufacturing such products.

[Please refer to the attachment for an overview of the Plant.]

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Reference

Overview of the Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy

Name Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell

Therapy, Central Research Laboratories

Address: 33-94, Enoki-cho, Suita City, Osaka Prefecture (at our Central Research

Laboratories)

Structure 12-m-tall steel construction with 2 aboveground levels

Building area 1,997m²

Total floor area 2,915m²

Construction start February 2017

Construction end March 2018

Construction cost Approximately 3.6 billion yen

Photo of the Plant

