

May 14, 2021

Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto,
Chairman & CEO
(TSE Mothers Code: 4593)

Cell Processing Center Establishment

HEALIOS K.K. (“Healios”) is pleased to announce that we have decided to establish a cell processing center (“CPC”) at the facility under consideration by the Foundation for Biomedical Research and Innovation in Kobe.

Healios is currently engaged in the R&D of immuno-oncology therapeutics using natural killer (NK) cells derived from allogeneic iPSCs and which possess specific functions that have been enhanced through gene editing technology (development code: HLCN061). Healios has also established next-generation “universal-donor” iPSCs with a reduced risk of immune rejection*¹ regardless of patient HLA type*², and is engaged in R&D related to various iPSC regenerative medicine products that utilize these universal donor cells as a starting material.

The CPC we plan to be establish will be used for the production of Healios’ investigational iPSC regenerative medicine products in compliance with GCTP*³/GMP*⁴ standards. The use of this CPC will allow Healios to efficiently produce NK cells to be used as investigational product and enable more rapid transition to clinical trials. At the same time, it will facilitate Healios’ internal consolidation of manufacturing technology and expertise required for the production of iPSC regenerative medicine products. By expediting our R&D activities inclusive of the efficient manufacturing of clinical trial product with the eventual goal of commercialization, we hope to bring new treatments and greater hope to patients around the world as quickly as possible.

This action has no impact on our company’s consolidated financial results for the current fiscal year. We will promptly make the necessary announcements in the event that any matter requiring disclosure arises in the future.

< Overview of the CPC >

(1) Address:

Minatojima-Minamimachi 6-3-5, Chuo-ku,
Kobe-city, Hyogo
Located within the Kobe Center for Medical
Innovation (KCMI)

(2) Total floor area: Approximately 240m²

(3) Purpose of use:

Production of investigational iPSC regenerative medicine
products that comply with GCTP/GMP standards

(4) Scheduled commencement of use of facility: January 2022



***1 Immune rejection**

This is a response involving the immune cells during the transplantation of cells or an organ derived from a different individual which results in the transplanted cells or organ (implant) being recognized as a foreign entity and attacked/rejected by the immune cells.

***2 HLA Type**

HLA (Human Leukocyte Antigen) is an important molecule expressed in all human cells that is involved in how our immune system functions. Any substance in an individual's body with HLA type that differs from the individual's own is recognized as a foreign substance, which triggers an immune response that rejects and attacks that substance. Therefore, ensuring a match of HLA type is extremely important in organ transplantation.

***3 GCTP**

An acronym for "Good Gene, Cellular, and Tissue-based Products Manufacturing Practice," GCTP is a set of standards governing the production management and quality control of regenerative medicine products.

***4 GMP**

An acronym for "Good Manufacturing Practice," GMP is a set of standards governing the production management and quality control of pharmaceutical products.

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