

March 27, 2026

Company Name: HEALIOS K.K.  
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(TSE Growth Code: 4593)  
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## **Announcement of Grant Approval for “Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities” under METI's FY 2024 Supplementary Budget**

As announced on July 16, 2025, in the press release titled “[Notice of Selection for FY2024 Supplementary Budget: “Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities” by METI](#)” HEALIOS K.K. was selected for this grant program (the “Grant”). After subsequent discussions with the Ministry of Economy, Trade and Industry (METI) regarding the details, we are pleased to announce that the decision to officially grant this subsidy has been finalized.

This Grant is positioned as a core initiative in the development of next-generation manufacturing infrastructure promoted by the government. Healios will receive approximately 7 billion yen in support to establish a manufacturing facility for advancing contract development and manufacturing services (CDMO) for regenerative medicine products.

### **1. Manufacturing Facility to Be Established**

With the support of this Grant, Healios will establish a Cell Processing Center (CPC) within the DP-Lab KOBE facility operated by Daiwa House Industry Co., Ltd. In this CPC, we aim to provide contract development and manufacturing services to pharmaceutical companies both domestically and internationally. Additionally, we plan to manufacture the somatic stem cell regenerative medicine product currently under development (Development Code: HLCM051) for acute respiratory distress syndrome (ARDS), trauma, and acute phase cerebral infarction as part of our CDMO business.



Image: Daiwa House Industry Co., Ltd. Website

- (1) Location:** Within DP-Lab KOBE, Minamimachi, Port Island, Chuo-ku, Kobe City, Hyogo Prefecture
- (2) Purpose:** Process development and manufacturing of regenerative medicine products in compliance with GCTP\*1/GMP\*2 standards
- (3) Expected Operational Start Date:** January 2028

## **2. Strategic Significance of the Approved Project**

With this grant approval, the Healios Group aims to establish a competitive advantage in the research, development, and manufacturing of iPS cells, somatic stem cells, and related products. We will accelerate the construction and commercialization of a global CDMO business infrastructure by implementing the following measures:

- Integration of world-class 3D large-scale cultivation technology with AI-driven process development
- Optimization of quality and cost through automation and closed-system platforms
- Development of an integrated system supporting initial development through commercial manufacturing
- Establishment of an internationally export-capable CDMO business for regenerative medicine products

## **3. Outlook**

Costs and grant income associated with this project will be recorded primarily as R&D expenses and other revenue in future financial statements. While some aspects of the equipment investment and process development covered by this Grant have already commenced during the fiscal year ending December 2025, we will promptly provide an update on the impact on fiscal year 2026 earnings as soon as it becomes clear.

\*1 GCTP: Good Gene, Cellular, and Tissue-based Products Manufacturing Practice - Standards for manufacturing and quality control of regenerative medicine products.

\*2 GMP: Good Manufacturing Practice - Standards for manufacturing and quality control of pharmaceuticals.

### **About HEALIOS K.K.:**

HEALIOS K.K. is Japan's leading clinical stage biotechnology company harnessing the potential of stem cells for regenerative medicine. It aims to offer new therapies for patients suffering from diseases without effective treatment options. Healios is a pioneer in the development of regenerative medicines in Japan and owns proprietary, global platforms utilizing both somatic stem cells and iPS cells.

In the somatic stem cell field, Healios is developing invimestrocel (HLCM051), a proprietary cell product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. Invimestrocel has been shown to exhibit powerful anti-inflammatory and immunomodulatory properties with applicability in a range of disease states, has been tested in hundreds of patients in late stage clinical trials, is manufactured consistently at scale in 3D bioreactors, and has demonstrated both safety and suggested efficacy in hundreds of patients across multiple indications. Healios is seeking to advance invimestrocel on a global basis for ARDS, ischemic stroke, and trauma.

In the iPSC regenerative medicine field, Healios is developing HLCN061, a next generation NK cell treatment for solid tumors that has been functionally enhanced through gene-editing. These cells have demonstrated robust anti-tumor efficacy in animal models, benefit from a scalable 3D bioreactor manufacturing process, and are currently being prepared for initial human testing in collaboration with Akatsuki Therapeutics. The company has also established a proprietary, gene-edited "universal donor" induced pluripotent stem cell line to develop next generation regenerative treatments in immuno-oncology, ophthalmology, liver diseases, and other areas of severe unmet medical need.

Healios was established in 2011 and has been listed on the Tokyo Stock Exchange since 2015 (TSE Growth: 4593). <https://www.healios.co.jp/en>