

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

Completion of DP-Lab KOBE Healios to Establish and Operate a Cell Manufacturing Facility

DP-Lab KOBE, a rental laboratory facility in which HEALIOS K.K. (“Healios”) plans to establish its cell manufacturing facility, the Healios / KOBE Cell Innovation Center (KCIC), has been completed, and a completion ceremony was held on October 19.

DP-Lab KOBE is a rental laboratory facility constructed by Daiwa House Industry Co., Ltd. within the Kobe Biomedical Innovation Cluster (KBIC). Designed as a next-generation research hub capable of accommodating state-of-the-art equipment, the facility aims to meet a wide range of research and development needs, particularly in the biotechnology and life sciences fields. Hardy TS Kagimoto, MD, Chairman and CEO, and Hironobu Kimura, Executive Officer and Head of Kobe Research Institute, attended the completion ceremony on behalf of Healios.



Second from left: Hardy TS Kagimoto, CEO



Guest Speech

1. Healios / KOBE Cell Innovation Center (KCIC)

Healios will establish KCIC, a cell manufacturing facility designed to serve global markets, within the newly completed DP-Lab KOBE. Operations are scheduled to commence in January 2028. Through KCIC, Healios will fully launch its contract development and manufacturing organization (CDMO) business. The facility will be equipped with 3D bioreactors, enabling Healios to establish a supply system for cell-based products manufactured using 3D cultivation technology.

KCIC will occupy the fourth through sixth floors of DP-Lab KOBE, with each floor providing 1,040 m² of space. The fourth floor will house process development (PD) and quality control (QC) areas, while the fifth and sixth floors will contain cell processing and manufacturing areas. This configuration will enable an integrated system supporting process development, quality evaluation, and GMP-compliant manufacturing.

The facility will be designed to comply not only with Japan’s GCTP Ministerial Ordinance, but also with PIC/S GMP, EU GMP, and U.S. FDA cGMP requirements. Healios aims to establish a manufacturing system that meets the regulatory requirements of Japan, the United States, and Europe.

KCIC is being developed with support from METI's "Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities" under the FY 2024 Supplementary Budget.

(Please refer to the press release dated July 16, 2025, titled ["Notice of Selection for FY2024 Supplementary Budget: 'Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities' by METI."](#))

2. Overview of **DP-Lab KOBE**, Where Healios Plans to Establish KCIC

1. Location: 6-3-10 Minamimachi, Port Island, Chuo-ku, Kobe City, Hyogo Prefecture
2. Total floor area: 9,144.42 m²
3. Structure: Six floors above ground, plus one penthouse level



Photo courtesy of Daiwa House Industry Co., Ltd.

3. Future Outlook

This matter will have no impact on Healios' consolidated financial results for the fiscal year ending December 31, 2026. We will promptly disclose any matters requiring disclosure should they arise.

About Healios:

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 HLCM051(invimestrocel), a proprietary cell product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. HLCM051 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 HLCM051 on a global basis for ARDS, trauma, and ischemic stroke. In the iPSC regenerative medicine field, Healios has developed HLCN061, a next generation NK cell treatment for solid tumors that has been functionally enhanced through gene-modification. These cells have demonstrated robust anti-tumor efficacy in animal models, benefit from a scalable 3D bioreactor manufacturing process. The development of AKT-01/HLCN061 is currently being led by our development partner, Akatsuki Therapeutics, Inc.,

in preparation for the initiation of clinical trials. Healios 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>

Contact:
IR & PR Division
HEALIOS K.K.
E-mail: ir@healios.jp