

July 27, 2026

Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto, Chairman & CEO
(TSE Growth Code: 4593)
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Healios Selected for the AMED “Project to Promote the Industrialization of Regenerative/Cell Medicine and Gene Therapy”

HEALIOS K.K. (“Healios”) is pleased to announce that our ongoing research and development efforts to Processes for Commercial Production of eNK* cells have been selected as a research project supported by AMED (Japan Agency for Medical Research and Development) for the fiscal year 2026 “Development of Basic Technologies for Industrialization of Regenerative Medicine and Gene Therapy (Project to Promote the Industrialization of Regenerative/Cell Medicine and Gene Therapy / Development Support Project)” (hereinafter referred to as “the Project”).

Publicly disclosed information: Development Support Project

[Development of Basic Technologies for Industrialization of Regenerative Medicine and Gene Therapy \(Project to Promote the Industrialization of Regenerative/Cell Medicine and Gene Therapy\) for fiscal year 2026 \(in Japanese\)](#)

Title:

Research and Development of a Commercial Manufacturing Process for AKT-01/HLCN061 (Genetically Modified iPS Cell-Derived NK Cells) for the Treatment of Pleural Mesothelioma

Max. subsidy amount:

79,933,000 yen per year (Including indirect costs)

(Total: Up to 240 million yen over three years from grant approval to the end of FY2028)

Note 1: In addition to direct expenses, indirect expenses may be included in eligible expenses, up to a maximum of 30% of the direct expenses.

Note 2: The grant amount will be the sum of two-thirds of the direct expenses and 0–30% of that amount, based on the total eligible expenses.

Our research and development have been selected as a project under the “Support for R&D to Promote Industrialization of Drug Discovery Seeds Aimed at Regenerative Medicine Products” program. For details of the subsidy amount, please refer to [the AMED website \(in Japanese\)](#).

1. Background and Objectives of Research and Development

With the aim of developing treatments for intractable cancers, Healios is collaborating with our development partner, Akatsuki Therapeutics, Inc., to advance the development of AKT-01/HLCN061 (natural killer (NK) cells derived from human (allogeneic) gene-transfected iPS cells), eNK cells), which have been genetically modified to enhance their antitumor effects. In this project, targeting pleural mesothelioma—a refractory rare cancer with a very poor prognosis—we aim to establish a scaled-up GMP production process using a 50-liter bioreactor with a view toward future commercial production.

Through this program, AMED aims to promote the commercialization of regenerative medicine products in the fields of regenerative medicine, cell therapy, and gene therapy. To this end, AMED will provide funding necessary for these development efforts to establish quality standards and manufacturing methods at the preclinical stage in accordance with regulatory requirements—as needed to proceed with corporate clinical trials in Japan or overseas.

In addition, AKT-01/HLCN061 project has also been selected as a research project supported by AMED for the fiscal year 2024 [“Development of Basic Technologies for Industrialization of Regenerative Medicine and Gene Therapy \(Project to Promote the Industrialization of Regenerative/Cell Medicine and Gene Therapy / Development Support Project\)”](#)(Healios announced on December 9, 2024).

2. Future Outlook:

This matter has no impact on our consolidated financial results of the fiscal year ending December 31, 2026 at this time. We will promptly announce any matters that should be disclosed in the future

*** eNK cells**

(Development code: AKT-01/HLCN061)

eNK cells are an iPSC-derived NK cell therapy with several functional enhancements achieved through gene-modification including enhanced recognition of and cytotoxicity towards cancer, improved persistence, increased capability to migrate to and infiltrate solid tumors, and the ability to recruit host immune cells. Healios has succeeded in developing eNK cells through its own research and has confirmed the anti-tumor effect of eNK cells in mice engrafted with human lung cancer cells and human liver cancer cells. In joint research with [the National Cancer Center Japan \(“the NCCJ”\)](#) Healios confirmed the antitumor effect of eNK cells in a PDX mouse disease model created using the NCCJ’s JPDX samples. Healios is also conducting joint research using eNK cells for hepatocellular carcinoma with [Hiroshima University](#) and for mesothelioma with [Hyogo Medical University](#). Akatsuki Therapeutics, Inc. and Healios are collaborating to continue to advance eNK cells in preparation for its first clinical trials. In addition to advancing eNK cells as a monotherapy and in combination with existing drugs, Healios is developing a dual CAR-eNK cell product, in which chimeric antigen receptors (CARs) that specifically recognize cancer antigens are introduced into the eNK cells to facilitate enhanced targeting of certain solid cancers. Healios is studying cancer immunocell therapy using CAR-eNK cells against brain tumors with [Kyushu University](#).

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>

About Akatsuki Therapeutics:

Akatsuki Therapeutics Inc. (Head office: 8-1 Kakuda-cho, Kita-ku, Osaka, Japan; President: Junya Yamazaki) is a biotechnology company developing next-generation cellular immunotherapies for cancer and other serious diseases. Akatsuki is leading the development of AKT-01/HLCN061, an iPSC-derived, gene-engineered eNK cell therapy for solid tumors, in collaboration with Healios, and is preparing the program for clinical trials, initially in pleural mesothelioma. Akatsuki aims to deliver scalable, off-the-shelf cell therapies to patients worldwide.