

August 14, 2023

Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto, Chairman & CEO
(TSE Growth Code: 4593)
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Healios Establishes Subsidiary for eNK Research and Development

HEALIOS K.K. (“Healios”) announced on July 11th, 2023 that [it decided to establish a subsidiary to promote the development of its eNK pipeline](#), with a focus on solid tumors, using NK cells derived from allogeneic iPSCs and whose specific functions have been enhanced with gene editing technology (development code: HLCN061 “eNK cells”). Today we are pleased to announce that we have determined the initial details of this subsidiary.

Outline of the subsidiary

Name of the subsidiary	eNK Therapeutic Inc.
Location	Chiyoda-ku, Tokyo
Representative director	Hikaru Saito, PhD
Business	Research, development, manufacturing and marketing of pharmaceutical products
Paid in capital	1 Yen
Date of establishment	August 14, 2023

There is no confirmed impact of this matter on the business results for the fiscal year ending December 31, 2023 at this time. We will promptly announce any matters that should be disclosed in the future.

About Healios’ eNK cells:

Healios eNK cells are a gene edited iPSC-NK cell therapy with several functional enhancements achieved through gene-editing including enhanced cytotoxicity towards cancer, improved capability to migrate 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 that eNK cells have anti-tumor effects in mice engrafted with human lung cancer cells, human mesothelioma cells and human liver cancer cells. In [joint research with the National Cancer Center Japan \(“the NCCJ”\)](#) we are evaluating the antitumor effects of eNK cells in a PDX mouse disease model created using the NCCJ’s JPDX samples. Furthermore, Healios is conducting joint research on cancer immunotherapies using eNK cells for hepatocellular carcinoma with [Hiroshima University](#) and for mesothelioma with [Hyogo Medical University](#). Healios is continuing with in vitro and animal testing of its eNK cell therapy in preparation for its first clinical trials. In addition, we are working on the development of a dual CAR-eNK cell product, in which chimeric antigen receptors (CAR) that specifically recognize cancer antigens are introduced into the eNK, with the aim of expanding the application of eNK cells to other solid tumors.

About Healios:

Healios 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, where it has established a proprietary, gene-edited "universal donor" induced pluripotent stem cell (iPSC) line to develop next generation regenerative treatments in immuno-oncology, ophthalmology, liver diseases, and other areas of severe unmet medical need. Healios' lead iPSC-derived cell therapy candidate, HLCN061, is a next generation NK cell treatment for solid tumors that has been functionally enhanced through gene editing. Its near-term pipeline includes the somatic stem cell product HLCM051, which has been evaluated in Japan in Phase 2/3 and Phase 2 trials in ischemic stroke and acute respiratory distress syndrome (ARDS), respectively. 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>