

February 9, 2023

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

**Presentation of the research results of Healios' eNK cells and UDCs
at the 22nd Congress of the Japanese Society for Regenerative Medicine**

HEALIOS K.K. ("Healios") announces that we will make poster presentations of our research results on eNK cells^{*1} and UDCs^{*2} at the 22nd Annual Meeting of the Japanese Society for Regenerative Medicine to be held at the Kyoto International Conference Center (<https://site.convention.co.jp/jsrm2023/>) from March 23 to 25, 2023.

We will present 6 posters for eNK cells and 1 poster for UDCs. Please see below for details.

[eNK cells]

Date of presentation: Thursday, March 23 16:50-17:50

Venue: Kyoto International Conference Center, 1F (Event Hall)

- ① Poster No.: P-03-1
Development of a method for mass production of transfected iPS cell-derived NK cells (HLCN061) using a 3D automated perfusion culture method
- ② Poster No.: P-03-3
Anti-tumor effect of iPSC-derived transgenic NK cells HLCN061 expressing high-affinity CD16 (F176V) on lung cancer and mesothelioma
- ③ Poster No.: P-03-4
Genetic engineering and quality control of clinical grade iPS cells as a source of HLCN061
- ④ Poster No.: P-03-5
Enhancement of anti-tumor effect against solid tumors by gene transfer in iPS cell-derived NK cells
- ⑤ Poster No.: P-03-6
Pharmacokinetic characteristics and antitumor effects of iPSC-derived transgenic NK cells (HLCN061)
- ⑥ Poster No.: P-03-7
Effect of IFN- γ on the anti-tumor effect of transgenic iPS cell-derived NK cells (HLCN061)

[UDCs]

Date of presentation: Saturday, March 25 16:50-17:50

Venue: Kyoto International Conference Center, 1F (Event Hall)

Poster No.: P-21-3

Clinical grade genetically engineered hypoinmunogenic human induced pluripotent stem cell line

*1 eNK cells

(Development code: HLCN061)

Healios' eNK cells are an iPSC-derived NK cell therapy with several functional enhancements achieved through gene-editing 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 is evaluating 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](#). Healios is continuing with in vitro and in vivo testing of its eNK cell therapy 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 to facilitate enhanced targeting of certain solid cancers.

*2 UDCs

UDCs are iPSC cells created using gene-editing technology that allows them to avoid and / or reduce the body's immune rejection response. The production of Healios' UDCs involve the removal of certain HLA genes that elicit a rejection response, the introduction of certain genes to improve immune evasion, and the addition of a suicide gene serving as a safety mechanism, each in an allogeneic iPSC cell. This next-generation technology platform allows for the creation of regenerative medicine products with enhanced safety and a lower risk of immune rejection, while preserving the inherent ability of iPSC cells to replicate themselves continuously and their pluripotency in differentiating into various other kinds of cells.

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>

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