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Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto, Chairman & CEO
(TSE Growth Code: 4593)
Contact: Richard Kincaid, Executive Officer CFO
(TEL: 03-5962-9440)

Joint Research Agreement with the National Cancer Center Japan using Healios' eNK Cells

HEALIOS K.K. ("Healios") announced today that it has entered a joint research agreement with the National Cancer Center Japan ("the NCCJ") for cancer immune cell therapy using Healios' allogeneic iPS cell-derived gene-edited NK cells (development code: HLCN061, "eNK cells").

Healios is developing next-generation cancer immunotherapies for solid tumors using eNK cells in the iPSC regenerative medicine field. In 2020, we started joint research with the NCCJ to clarify the characteristics of solid tumors in which eNK cells exert antitumor effects. In 2021, as a result of this joint research, we confirmed expression of molecules recognized by gene-edited NK cells using NCCJ-PDX from multiple types of human solid cancers (lung cancer, pancreatic cancer, breast cancer, and mesothelioma). Based on the results of this research, we plan to evaluate the antitumor effects of eNK cells in a PDX mouse disease model created using the NCCJ's J-PDX samples.

In addition to the PDX mouse model evaluation that will take place at the NCCJ, Healios is continuing to evaluate the anti-tumor effect of eNK cells in mice with lung and liver cancer through its own laboratory activities and through its joint research with Hiroshima University. In addition, we have established a highly efficient and stable mass production technology for eNK cells using a 3D bioreactor production system and are preparing to launch operations of a cell processing center (CPC) for the manufacturing of eNK cell clinical trial product.

Even though the advent of molecular targeted drugs and cancer immunotherapy has improved treatment outcomes for some cancer patients, the efficacy of existing treatments for solid tumors remains poor. Healios is committed to our continued research and development of effective

treatments for solid cancer patients.

Healios will pay the joint research expenses under this agreement. This agreement does not have a material impact on our consolidated financial results for the current fiscal year. We will promptly make an announcement on any matter that requires disclosure in the future.

■Outline of the Collaboration Partner

・Name of the Collaborator: The National Cancer Center Japan
・Address:5-1-1 Tsukiji, Chuo-ku, Tokyo Japan
・Representative: Hitoshi Nakagama, M.D., D.M.Sc. President

*1 Natural killer (NK) cells

Natural killer (NK) cells are a subset of lymphocytes, a type of white blood cell. NK cells play a central role in a cell mediated defense system that human bodies naturally have, and attack cancer cells and virus-infected cells. The expected efficacy of treatments using NK cells includes life-extension, promotion of healing, relief of symptoms, and improvement of quality of life.

* 2 PDX model

PDX (Patient-Derived Xenograft) model is a patient tumor tissue transplant model in which a tumor tissue piece derived from a patient is transplanted into an immunodeficient mouse to reproduce a tumor. It is used in preclinical drug discovery research because it reproduces a condition close to that observed in a clinical setting. The PDX model retains the characteristics of the cancer tissue and can bring high accuracy in predicting the therapeutic effect of an anticancer drug.https://www.ncc.go.jp/en/ri/department/pharmacology_therapeutics/20180821104146.html

About National Cancer Center Japan:

Founded in 1962 as a national institution to serve as a base for cancer treatment and research in Japan, it is a cancer-based hospital that has been a strong leader in cancer treatment and research in Japan. The NCCJ was incorporated into an independent administrative agency in 2010, designated as a national research and development corporation in 2015, and has a central hospital (Tsukiji Campus) and east hospital (Kashiwa Campus) designated as core clinical research hospitals under the Medical Law. It is promoting development research in collaboration with the Research Institute.

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 is currently being 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