January 20, 2025

Company Name:	HEALIOS K.K.
Representative:	Hardy TS Kagimoto, Chairman & CEO (TSE Growth Code: 4593)
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The Conclusion of a Master Collaboration Agreement and License Option Agreement with Akatsuki Therapeutics Inc.

HEALIOS K.K. ("Healios") today announce that we have entered into a Master Collaboration Agreement (the "Collaboration Agreement") and a License Option Agreement (the "Option Agreement") to promote the research and development of next-generation immune cell therapies for cancer and other diseases using eNK cells*[1] with Akatsuki Therapeutics, Inc. (Head office: 5-22-33 Higashigotanda, Shinagawa-ku, Tokyo, Japan; President: Kenichiro Yamaguchi / Hikaru Saito; wholly-owned subsidiary of Saisei Ventures LLC; "Akatsuki").

1. Outline of the Agreements

(1) Collaboration Agreement

Under the Collaboration Agreement, Akatsuki will take the lead in the research and development activities for eNK cells, which have been carried out solely by Healios until now. Healios will undertake research and development tasks as commissioned by Akatsuki. Strategically, the collaboration allows for the efficient use of resources and flexibility with respect to the procurement of funds for the Healios Group as a whole. This transition will also reduce Healios' financial burden, with a projected reduction of approximately 770 million yen in the fiscal year ending December 2025 and an anticipated initial payment by Akatsuki to Healios of approximately 360 million yen by February 2025. The relationship is anticipated to persist for multiple years, to and through the generation of first in human data for eNK cells. Akatsuki will also lead the strategic development and partnering initiatives for the eNK cell program. Healios and Akatsuki will establish a Joint Steering Committee (JSC) to oversee and guide the research and development strategy for this pipeline. Healios has cultivated research, development and manufacturing technology capabilities in the field of regenerative medicine for many years, and we will use this experience and our resources in support of this research and development.

As announced on December 9, 2024 in the press release titled "Healios Selected for the AMED 'Project to Promote the Industrialization of Regenerative/Cell Medicine and Gene Therapy'", the research and development using eNK cells has been adopted as a research project supported by the "Fundamental Technology Development Project for Industrialization of Regenerative Medicine and Gene Therapy" for fiscal year 2024, for which the National Institutes of Health and Medical Devices (AMED) solicited applications from the public. Healios will continue to take the lead in promoting the research and development of this research project.

(2) Option Agreement

Healios has granted Akatsuki an option to enter into a license agreement to research, develop, manufacture, and market eNK cells in all therapeutic areas, particularly in the field of oncology, and has agreed to acquire Akatsuki's shares and stock acquisition rights upon the entering of a

license agreement resulting from the exercise of the option. The details of these issuances and other details will be determined after further discussions between the two companies. In addition, the two companies have agreed on the key terms and conditions of a license agreement that would result from the exercise of the option, including royalties, development and sales milestones.

As described in "Healios and Saisei Ventures Enter into a Letter of Intent and Establish Subsidiary for eNK Research and Development" dated July 11, 2023 and "Healios Establishes Subsidiary for eNK Research and Development" dated August 14, 2023, Healios and its consolidated subsidiary Saisei Ventures LLC ("Saisei") previously established eNK Therapeutics Inc. ("eNK Therapeutics") and considered an investment from a fund managed by Saisei. However, with the establishment of Akatsuki, the research and development of therapeutics using eNK cells will be led by Akatsuki, with the aim of launching them in the global market, including the United States, which is the largest market in the world. Therefore, the discussions with Saisei regarding the investment in eNK Therapeutics are scheduled to be terminated.

2. Future outlook

Akatsuki's financial statements are scheduled to be consolidated starting from the first quarter of the fiscal year ending December 2025, and transactions between Healios and Akatsuki will be eliminated upon consolidation. As for other matters related to this, there are currently no confirmed impacts on the performance for the fiscal year ending December 2025. Should any matters requiring disclosure arise in the future, we will provide timely updates.

About 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 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. Through its collaboration with Akatsuki Therapeutics, Healios is continuing 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 to facilitate enhanced targeting of certain solid cancers.

About Saisei Ventures:

Saisei Ventures is a life science venture capital firm dedicated to building next-generation companies in the healthcare sector. We create ventures that start from bold ideas and empower dynamic entrepreneurs by providing technical, operational, and financial guidance. Our approach combines Western expertise and Japanese innovations to build globally competitive companies that will have the greatest impact on patient lives. With operations in Japan and the United States, Saisei aims to enhance the value of its portfolio by leveraging its unique networks and the institutional advantages of both countries. For more information, visit

https://www.saiseiventures.com

About Akatsuki:
Akatsuki Therapeutics Inc. is developing innovative cellular immunotherapies with the potential to transform the treatment of cancer and other serious diseases. Our lead program harnesses advanced genetic enhancements, cellular reprogramming, and scalable manufacturing to address the limitations of existing cell therapy approaches. Driven by a mission to create accessible, off-the-shelf solutions, we aim to deliver life-changing therapies that will improve worldwide patient access and improve the standard of care. At Akatsuki Therapeutics, we are committed to advancing the next generation of cellular immunotherapies to usher in a new dawn for patients and their families.

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 MultiStem® (HLCM051), a proprietary cell product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. MultiStem 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 MultiStem 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-editing. These cells have demonstrated robust anti-tumor efficacy in animal models, benefit from a scalable 3D bioreactor manufacturing process, and are currently being prepared for initial human testing. The company 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