

Company Name: HEALIOS K.K.  
 Representative: Hardy TS Kagimoto, Chairman & CEO  
 (TSE Growth Code: 4593)  
 Contact: Richard Kincaid, Executive Officer CFO  
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## **Basic Business Alliance Agreement and Bond Purchase Agreement with Alfresa Corporation**

HEALIOS K.K. (“Healios”) today announces that it has resolved to enter into a Basic Business Alliance Agreement (“Basic Business Agreement”) and the First Series of Straight Bonds and Second Series of Straight Bonds Purchase Agreement (“Bond Purchase Agreement”) with Alfresa Corporation (“Alfresa” <https://www.alfresa.co.jp/> only in Japanese) concerning the distribution and sale of products owned by Healios.

### **1. Outline of Basic Business Agreements**

#### **(1) Business alliance**

The Basic Business Agreement grants Alfresa the following preferential rights in Japan:

- a) Exclusive rights for the wholesale distribution of Healios' pipeline products including MultiStem<sup>®</sup> (HLCM051)<sup>\*1</sup>, a somatic stem cell regenerative medicine product, and to transport and deliver the investigational drug for these pipeline products;
- b) Rights for commercialization and exclusive distribution of MultiStem culture medium supernatant and products derived from the culture medium supernatant (including products co-developed by Healios with third parties); and
- c) Rights for commercialization and exclusive sale of SIFU<sup>™</sup> (Secure Integrated Freezer Unit)<sup>\*2</sup> ("SIFU"), a cell product cryopreservation device.

The details of the above will be discussed and a separate contract will be signed in the future.

#### **(2) Bond issuance**

In conjunction with the execution of the Basic Business Agreement, Healios will enter into a Bond Purchase Agreement with Alfresa and issue Healios' first and second series of straight bonds as per the following.

#### Outline of the issuance of the first and second series of straight bonds

(1) Name of bonds	Healios first series of straight bonds Healios second series of straight bonds
(2) Total amount of bonds	First series: 800,000,000 yen Second series: 800,000,000 yen
(3) Amount of each bond	100,000,000 yen
(4) Payment date	June 28, 2024
(5) Redemption date	First series: June 28, 2027 Second series: June 28, 2030
(6) Interest rate	2% per annum
(7) Redemption amount	100 yen per each 100 yen amount of bonds

(8) Underwriter	Alfresa Corporation
(9) Use of funds	Research for MultiStem culture medium supernatant and development of SIFU, and allocation to other operating expenses.

### **(3) Asset Transfer Agreement or Intellectual Property License Agreement**

Under the Basic Business Agreement, Healios has agreed that if the Bonds are not redeemed on the redemption date stipulated in the terms and conditions of the issuance of the Bonds, or if the Bonds lose their benefit of the term, Healios shall immediately transfer to Alfresa certain inventory or stock of the supernatant, certain intellectual property rights, etc. related solely to this culture supernatant held by Healios, and the SIFU inventory and stock, or intellectual property rights, etc. covering SIFU designated by Alfresa and, if necessary, Healios has agreed to enter into an intellectual property license agreement that grants Alfresa or its affiliates a non-exclusive license to manufacture MultiStem as a material for culture supernatant in Japan.

## **2. Purpose of the Business Alliance**

Healios is advancing MultiStem for Acute Respiratory Distress Syndrome (ARDS), ischemic stroke, and other indications, with the aim of commercializing the product globally. Healios is also conducting research aimed at realizing sales of culture supernatant generated in the process of cell culture of Healios owned products, due to the large increase in the production volume of these products. In addition, Healios is promoting research and development of SIFU as a freezing and storage device for cell products, which is expected to be a promising solution for the logistical issues faced by the cell and gene therapy industry related to transportation and storage at ultra-low temperatures. SIFU is positioned as a future business domain for the company.

Alfresa has a social mission to deliver “safe, secure, and high-quality” pharmaceuticals and other products needed by its customers and patients, when, how, and where they are needed. In order to contribute to the stable supply of regenerative medicine products, Alfresa has established a regenerative medicine distribution station and a regenerative medicine product storage facility to create an environment in which it can undertake distribution, and is also continuing to improve its expertise in transportation and delivery.

Through this Business Alliance, the two companies will combine and maximize their know-how and technologies to, as soon as possible, provide treatments for patients suffering from diseases for which there are no effective treatments, with the aim of practical application and expansion of regenerative medicine in Japan.

In concluding this Basic Business Agreement, Tadahisa Kagimoto, MD, Chairman and CEO of Healios, made the following comment: "This Basic Business Agreement paves the way for us to deliver our drugs under development to patients through Alfresa, and accelerates our delivery of MultiStem culture supernatant, which will contribute to our near-term profitability, to medical institutions in Japan. We also granted Alfresa preferential rights to deploy SIFU cryopreservation equipment for ultra-low temperature cellular products in warehouses, transport vehicles, and hospitals in Japan. As a leading company in cell therapy products, we will continue our management efforts to contribute to this important value chain."

## **3. Future Outlook**

The execution of the Basic Business Agreement will have no impact on our consolidated financial results at this time. The issuance of the bonds under the Bond Purchase Agreement

is expected to result in the recording of 16 million yen in interest on the bonds in the year ending December 31, 2024. We will promptly announce any matters that should be disclosed in the future.

**\*1 MultiStem<sup>®</sup>**

MultiStem (HLCM051) is a somatic stem cell regenerative medicine 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 across multiple indications. MultiStem is a proprietary technology wholly owned by Healios. Healios has a long history developing MultiStem. It originally added MultiStem to its pipeline in 2016 through an exclusive license to develop and distribute the product to treat ischemic stroke in Japan. Further, in 2018 Healios expanded its license to include development and distribution to treat ARDS in Japan, and in 2023 it expanded its ARDS license to include global territories. Having acquired the full technology platform in April 2024, Healios is seeking to advance MultiStem on a global basis for ARDS, ischemic stroke and trauma.

**\*2 SIFU<sup>™</sup>**

SIFU (“Secure Integrated Freezer Unit”) is an advanced frozen cell product storage device which is a promising solution to the logistical challenges faced by the cell and gene therapy industry due to the need for extremely low temperature storage, and the precise handling and streamlined management of highly valuable frozen inventory. Healios owns this technology, including its patents, plans, and prototype units. The SIFU technology not only offers a potential method for efficient commercial distribution of MultiStem, but a platform for the broader market.

**About Alfresa:**

Alfresa, as a social infrastructure for the distribution of medical supplies, which are life-related products, delivers “safe, reliable, and high-quality” medical supplies needed by medical institutions and patients, and also promotes multifaceted initiatives to solve social issues, such as supporting the efficiency of the medical field through the use of digital tools.

Name of the company: Alfresa Corporation

Location: Kanda Mitoshiro-cho, Chiyoda-ku, Tokyo

Representative: Yusuke Fukujin, President and Representative Director

<https://www.alfresa.co.jp/> (only in Japanese)

**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 ischemic stroke, ARDS, and trauma.

In the iPSC regenerative medicine field, Healios' lead candidate, HLCN061, is 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>