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Healios and Saisei Ventures Enter into a Letter of Intent and Establish Subsidiary for ARDS Treatment Development

HEALIOS K.K. (“Healios”) is in the process of preparing for a clinical trial in Japan to further test HLCM051^{*1}, a somatic stem cell regenerative medicine product, for Acute Respiratory Distress Syndrome (ARDS)^{*2}. Healios is executing on its strategy to advance its therapeutic programs while leveraging efficient external funding sources involving investments from third parties including project finance, grants and partnerships. Consistent with this strategy, on December 14, 2022, Healios announced a Letter of Intent with Mitsubishi UFJ Capital in relation to project finance for ARDS development in Japan (See “[Healios and Mitsubishi UFJ Capital Enter into a Letter of Intent for Joint Development for HLCM051 for ARDS](#),” hereinafter referred to as the “MUFJ LOI”). Today, Healios is pleased to announce that it has decided to establish a subsidiary to promote the development of this pipeline and has concluded an additional letter of intent with Saisei Ventures LLC (hereinafter referred to as “Saisei”), whereby Saisei will seek to commit invested capital of 1 billion yen or more to the subsidiary in the future from Saisei managed funds.

1. Outline of letter of intent with Saisei Ventures

With the aim of accelerating the development of HLCM051 for ARDS, Healios and Saisei have agreed that, upon entering into a definitive agreement, Saisei would make commitments to invest in the subsidiary described further in 2. below from Saisei managed funds and would provide support to the subsidiary with respect to activities to obtain non-dilutive grant funding. It is anticipated that a total of over 1 billion yen would be committed to the subsidiary as investments from Saisei funds.

Saisei Ventures is a venture capital firm that aims to nurture next-generation companies in the healthcare field. As announced [on Feb 6, 2023](#), Japan Investment Corporation committed \$30 million of capital to Saisei’s flagship fund. In addition, as further [announced on May 17, 2023](#), Saisei was selected as one of nine certified venture capital firms in the fiscal year 2023 “Strengthening Program for Pharmaceutical Startup Ecosystem (Approval of Venture Capital)” (2nd round), by the Japan Agency for Medical Research and Development (“AMED”), allowing for Saisei backed companies to apply for certain AMED grant funding opportunities.

2. Establishment of subsidiary

[On March 2, 2023](#), Healios announced the outline of a new clinical trial to investigate the efficacy and safety of HLCM051, a somatic stem cell regenerative medicine product, for ARDS. [On July 5, 2023](#) Healios further announced that it agreed with the PMDA regarding the use of 3D bioreactor based product in this clinical trial, establishing a manufacturing path

that is stable, scalable and cost efficient. As we prepare for trial initiation, we will establish a subsidiary and continue to advance discussions with both MUFJ and Saisei towards the conclusion of definitive agreements.

The subsidiary to be established will initially be wholly owned by Healios and is scheduled to be established in July 2023, with the business of research, development and marketing of pharmaceutical products. The name of the subsidiary is ProcellCure Inc. and its location is Chuo-ku, Kobe, Hyogo Prefecture. The representative director is Hikaru Saito, PhD, a senior member of Saisei's investment team.

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.

*** 1 HLCM051**

HLCM051 is a somatic stem cell regenerative medicine product. Healios added it to its pipeline by signing an exclusive licensing agreement with the United States based Athersys, Inc. ("Athersys") in January 2016, whereby Healios acquired rights to develop and distribute Athersys' proprietary stem cell product MultiStem® to treat ischemic stroke in Japan. Further, in June 2018 Healios and Athersys expanded their collaboration broadly, and as part of this expansion Healios acquired the development and distribution licenses, and later a manufacturing license, to use MultiStem to treat ARDS in Japan.

*** 2 ARDS**

ARDS is a general term for the symptoms of acute respiratory failure suddenly occurring in seriously ill patients. The major causes are severe pneumonia, septicemia, trauma etc. Inflammatory cells are activated in response to these diseases or injuries, causing damage to the tissue of the lungs. As a result, water accumulates in the lungs, leading to acute respiratory failure. According to the ARDS treatment guideline 2016, the mortality rate is approximately 30 to 58%. The number of patients in Japan is estimated to be approximately 28,000 (Healios estimate based on epidemiological data on incidence and population statistics). Artificial respiration using an endotracheal tube or mask is used to treat respiratory failure in an intensive care unit.

About Saisei Ventures:

Saisei Ventures is a leading venture capital firm dedicated to building next-generation companies in the healthcare sector. It aims to partner with passionate bio-entrepreneurs to develop and implement business strategies that will generate strong proof of concept, clinical validation, and market value. With operations in Japan and the United States, Saisei aims to enhance the value of its portfolio companies by leveraging its unique networks in and the institutional advantages of both countries. Saisei's first fund, Saisei Bioventures L.P., is focused on building revolutionary cell and gene therapy and regenerative medicine companies from foundational technologies originating from Japan. For more information, visit <https://www.saiseiventures.com>

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>