

December 14, 2022

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Healios and Mitsubishi UFJ Capital Enter into a Letter of Intent for Joint Development for HLCM051 for ARDS

HEALIOS K.K. (“Healios”) announces that Healios and Mitsubishi UFJ Capital Co., Ltd. (Head Office: Chuo-ku, Tokyo; President: Shinsuke Sakamoto; hereinafter referred to as "Mitsubishi UFJ Capital") have entered into a letter of intent (hereinafter referred to as the "Agreement") regarding the establishment of a new company to be formed in the future with investment from Mitsubishi UFJ Capital and the conclusion of a joint development agreement between Healios and the new company under the following conditions in order to accelerate the development of HLCM051^{*1} as a somatic stem cell regenerative medicine product for acute respiratory distress syndrome (ARDS).^{*2}

In developing a treatment for ARDS, Healios conducted a Phase II efficacy and safety trial for patients with pneumonia induced ARDS (trial name: ONE-BRIDGE). In August and November 2021, the Group announced results for the evaluation items on the 90th and 180th days after administration of HLCM051 in ONEBRIDGE, which showed favorable results in terms of efficacy and safety. Subsequently, at the end of March, Healios held a pre-application consultation with the PMDA to obtain guidance and advice on applying for approval. Although a certain level of agreement was reached on the efficacy and safety of the product, Healios received advice that the data package should be reinforced to apply for approval. Accordingly, Healios is continuing discussions with the regulatory authorities.

Under these circumstances, Healios and Mitsubishi UFJ Capital have entered into the Agreement to establish a new company to support the development of a treatment for ARDS and to conclude a joint development agreement between Healios and the new company. The new company will be established to provide advice and development funding, and its operating expenses will be covered by investments from Mitsubishi UFJ Capital, the lead venture capitalist, and other investors. Since these funds will be raised by the new company, there will be no dilution of Healios' shares due to an issuance of new shares, etc. The conclusion of the joint development agreement is subject to the completion of discussions with the regulatory authorities on the plan for data reinforcement, etc., necessary for the application for approval of HLCM051 for ARDS, and agreement by Mitsubishi UFJ Capital on the details of such plan, etc.

There is no confirmed impact of this matter on the business results for the fiscal year ending December 31, 2022 at this time. We will promptly announce any matters that should be disclosed in the future.

* 1 HL051

HL051 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%. Artificial respiration using an endotracheal tube or mask is used to treat respiratory failure in an intensive care unit.

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 HL051, 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>