

February 5, 2021

Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto,
Chairman & CEO
(TSE Mothers Code: 4593)

Announcement of basic business agreement with SPLine Corporation regarding sales of pharmaceuticals

HEALIOS K.K. (“Healios”) is pleased to announce that it has concluded a basic business agreement with SPLine Corporation (“SPLine”), a wholly-owned subsidiary of MEDIPAL HOLDINGS CORPORATION (“MEDIPAL”) concerning the sales of pharmaceuticals aimed for commercialization.

Healios is currently conducting two clinical trials using stem cell product HLCM051* for ischemic stroke and acute respiratory distress syndrome (ARDS) patients in Japan. In advance of potential approval applications for HLCM051, and for the purposes of being able to promptly develop sales activities, Healios has entered into a basic business agreement with SPLine regarding the sale of pharmaceutical products.

The MEDIPAL Group has storage facilities and delivery systems capable of distributing specialty drugs, including regenerative medicine products. It also boasts multiple achievements in distributing products that require high-performance logistics systems, such as special temperature control. Its notable achievements in cell medicine distribution include establishing the first wholesale distribution system in Japan for both allogeneic and autologous cells. Healios and SPLine will utilize the MEDIPAL Group's distribution infrastructure to prepare for the commercialization of HLCM051.

*** 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 to use MultiStem to treat ARDS in Japan.

About MEDIPAL HOLDINGS CORPORATION

Location: Chuo-ku, Tokyo

Representative: Shuichi Watanabe, Representative Director, President, and CEO

Line of Business: As a holding company, MEDIPAL controls, administers and supports the operating activities of companies in which it holds shares in the Prescription Pharmaceutical Wholesale Business; the Cosmetics, Daily Necessities and OTC Pharmaceutical Wholesale Business; and the Animal Health Products and Food Processing Raw Materials Wholesale Business, and conducts business development for the MEDIPAL Group.

About SPLine Corporation

Location: Chuo-ku, Tokyo

Representative: Atsushi Takumiya, Representative Director, President, and CEO

Line of Business: SPLine proposes specialty pharmaceutical distribution plans, connecting pharmaceutical manufacturers with the operating companies of the MEDIPAL Group, and planning distribution systems tailored to the characteristics of each specialty pharmaceutical product. Using various bases, including the ALCs (Area Logistics Centers) and FLCs (Front Logistics Centers)—the MEDIPAL Group’s highly functional distribution centers—SPLine provides high-quality services uniformly throughout Japan based on strict quality control, stably delivering pharmaceutical products to medical institutions through a safe and secure distribution network.

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. 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 Mothers: 4593). <https://www.healios.co.jp/en/>.

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