



December 2, 2013

Healios K.K. Dainippon Sumitomo Pharma Co., Ltd.

Healios and Dainippon Sumitomo Pharma form an alliance in regenerative medicine and cell therapy --- Joint development of the world's first regenerative medicine/cell therapy business based on iPS cell technology ---

Healios K.K. ("Healios") (Head Office: Tokyo, Japan; President: Hardy T S Kagimoto, MD; formerly known as "Retina Institute Japan KK") and Dainippon Sumitomo Pharma Co., Ltd. ("DSP") (Head Office: Osaka, Japan; President: Masayo Tada) announce today that the two companies have signed an agreement on the joint development in Japan of iPS cell-derived retinal pigment epithelial cells ("RPE cells") for the treatment of age-related macular degeneration and other eye diseases.

Under the terms of the joint development agreement, Healios and DSP will launch clinical studies at an early date and seek the manufacturing and marketing approval for indications of age-related macular degeneration and other diseases under the New Pharmaceutical Affairs Law of Japan so as to make iPS-derived RPE cells available as cell therapy early. The two companies will form a joint development committee to decide the strategy, work assignments and other necessary matters. Healios and DSP will co-develop iPS cell-derived RPE cell products ("RPE cell products") in Japan with the fund of maximum 5,200 million yen borne by DSP to cover the cost of development. Healios will obtain the manufacturing and marketing approval and market RPE cell products.

The two companies have also signed a joint venture agreement today in order to jointly manufacture and promote the RPE cell products commercialized in the future through the joint development. The joint venture company is scheduled to be established in February 2014.

In a related move, the two companies have entered into a license agreement today under which various technologies and know-hows of Healios including mass culture of the iPS cell-derived RPE cells are licensed to DSP. The license and the resulting access to the Healios technology will help DSP strengthen its activities in the field of regenerative medicine and cell therapy. For the grant of the license, Healios will receive from DSP a down payment of 500 million yen and future milestone payments of maximum 1.1 billion yen.

Both parties look forward to working together to commercialize the iPS cell products so as to deliver therapeutic measures to the patients with age-related macular degeneration and other refractory retinal diseases as early as possible.

* The two companies made a joint announcement on March 28, 2013 concerning conclusion of an agreement for DSP's equity participation in Healios and initiation of discussions for alliance to put iPS cell technology into practical use.

<Reference information>

Scope of the joint development agreement

- (1) Products: iPS cell-derived RPE cells products
- (2) Indications: Eye diseases (wet AMD and others)
- (3) Territory: Japan

Outline of the joint venture company

- (1) Company name: (To be determined)
- (2) Location: (To be determined)
- (3) Representative director: Hardy T S Kagimoto, MD
- (4) Business scope: Manufacturing and sale and other activities of pharmaceuticals, medical equipment, regenerative medicine products and other products in the field of eye diseases
 - * The joint venture company will acquire license from Healios and DSP on the eventual outcomes of the joint development program. It will pay a consideration for the license of such outcomes evenly to the two companies.
- (5) Paid-in capital: 50 million yen
- (6) Date of establishment: February 2014 (planned)
- (7) Shareholding: Healios 50%; DSP 50%

An outline of Healios:

Healios is a RIKEN Venture approved as such by RIKEN, an independent administrative agency. Based on a patent license granted on RIKEN's invention born in Japan, Healios is engaged in the development of new treatment methods for age-related macular degeneration through implantation of RPE cells that are differentiation guided from iPS cells. Further, it seeks to make a successful development of such treatment methods as the stepping stone to develop technologies for photoreceptor cell implantation, retina regeneration pharmaceuticals and test methods so that current refractory retinal diseases will be made curable.

An outline of DSP:

DSP focuses its research and development on psychiatry & neurology and oncology areas, where high unmet medical needs exist in order to channel its energies into innovative drug discovery. By the same token, DSP seeks to apply leading-edge science such as iPS cells to drug discovery and strengthen activities in regenerative medicine and cell therapy to develop medicines for refractory diseases.

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