Sumitomo Dainippon Pharma

News Release

June 13, 2019

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma announces Changes to Agreement on Joint Development of Treatments for Eye Diseases Using iPS Cell-derived Retinal Pigment Epithelial Cells in Japan

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) today announced that it has concluded an agreement ("Change Agreement") to make changes to the original agreements ("Original Agreements") with Healios K.K. (Head Office: Tokyo, Japan; Chairman and CEO: Hardy TS Kagimoto, MD) for the joint development and other joint activities in Japan of iPS cell-derived retinal pigment epithelial cells ("RPE cells") for the treatment of age-related macular degeneration and other eye diseases.

< Summary of Change Agreement>

(1) Changes to Joint Development Agreement

In the Original Agreements, Healios was the party primarily responsible for conducting clinical studies on the RPE cell product and submitting applications for manufacturing and marketing approval. However, according to the Change Agreement, Sumitomo Dainippon Pharma will become the party primarily responsible for conducting clinical studies and both parties will be able to submit applications for manufacturing and marketing approval based on the results of the clinical studies. Also, based on the assumption that Healios would develop the RPE cell product, Sumitomo Dainippon Pharma was to bear a maximum of ¥5.2 billion of the development costs. However, in accordance with the terms of the Change Agreement, the burden of development costs will be changed to a flexible framework after the Change Agreement is concluded.

After discussion by both parties and taking the situation into account, which necessitated a review of how the management resources of Healios should be allocated, it was concluded to make change that Sumitomo Dainippon Pharma, which is aiming at developing three-dimensional retinal tissue products, will be the party primarily responsible for the development of the RPE cell product.

(2) Changes to License Agreement

Under the Original Agreements, development milestone payments by Sumitomo Dainippon Pharma to Healios were a maximum of ¥1.6 billion but in the Change Agreement this has been changed to a maximum of ¥1.0 billion. Also, the territory covered by the license agreement of the RPE cell product was previously confined to Japan (Exclusive) but other countries (Non-exclusive) have now been added.

(3) Changes to Joint Venture Agreement

In the joint venture agreement, the manufacture and sales promotion activities for the RPE cell product was to be outsourced to Sighregen Co., Ltd., which was established in February 2014 with Healios and Sumitomo Dainippon Pharma each taking a 50% stake. In the Change Agreement, the outsourcing of sales promotion activities has been removed.

Continuing our efforts toward the future commercialization of the RPE cell product using iPS cells in collaboration with Healios, Sumitomo Dainippon Pharma aims to deliver therapies to patients suffering from age-related macular degeneration and other refractory retinal diseases as quickly as possible.

* On March 28, 2013, Sumitomo Dainippon Pharma and Healios jointly announced the conclusion of an agreement on investment in Healios by Sumitomo Dainippon Pharma and initiation of discussions toward collaboration on commercialization of a product applying iPS cell technologies, and on December 2, 2013, a joint development agreement and other agreements for RPE cell-based treatments for age-related macular degeneration and other eye diseases were concluded in Japan.

Contact:
Corporate Communications
Sumitomo Dainippon Pharma Co., Ltd.
TEL: +81-6-6203-1407 (Osaka); +81-3-5159-3300 (Tokyo)