

Alliance for Japanese market
- iPS cell technology into practical use -

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

Background

March 28, 2013

- ◆ Capital alliance: DSP took a ¥1.5billion stake in Healios (former RIJ)
- ◆ Basic agreement: Discuss alliance for practical use of iPS cell technology



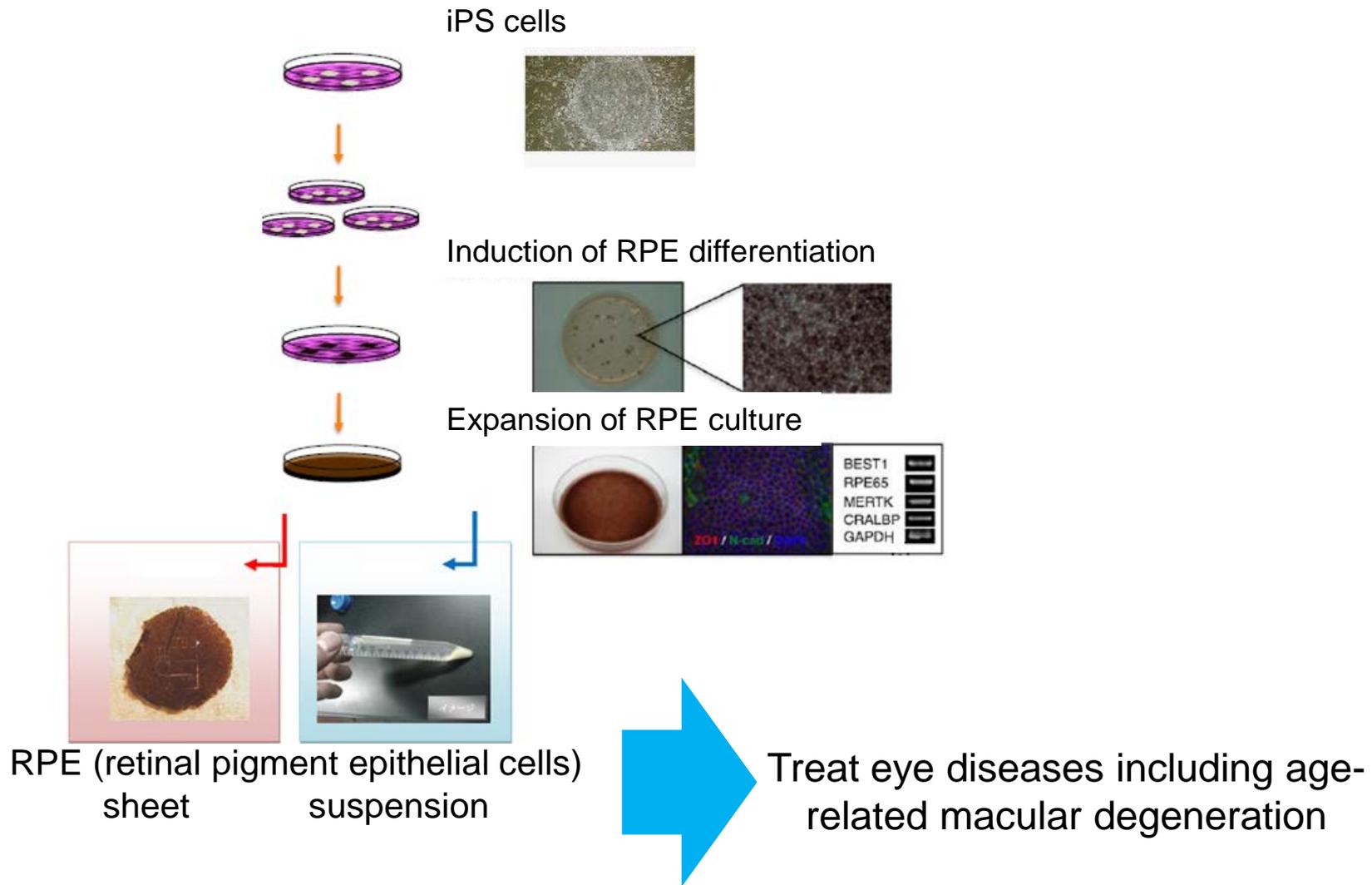
Discussion about alliance between the two companies in and outside Japan for practical use of iPS cell technology for the treatment of retinal disorders



December 2, 2013

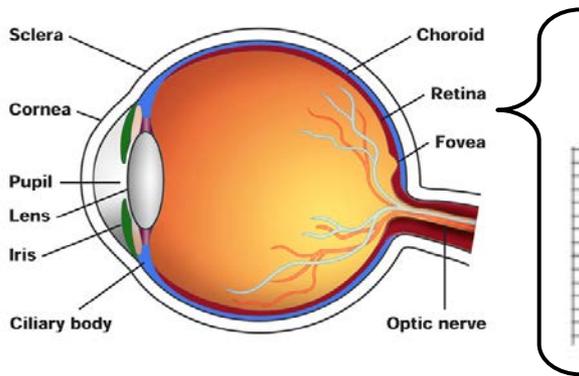
Signed an Alliance Agreement to put iPS cell technology into practical use for the treatment of eye diseases in Japanese market

Manufacture of iPS cell-derived retinal pigment epithelial cells



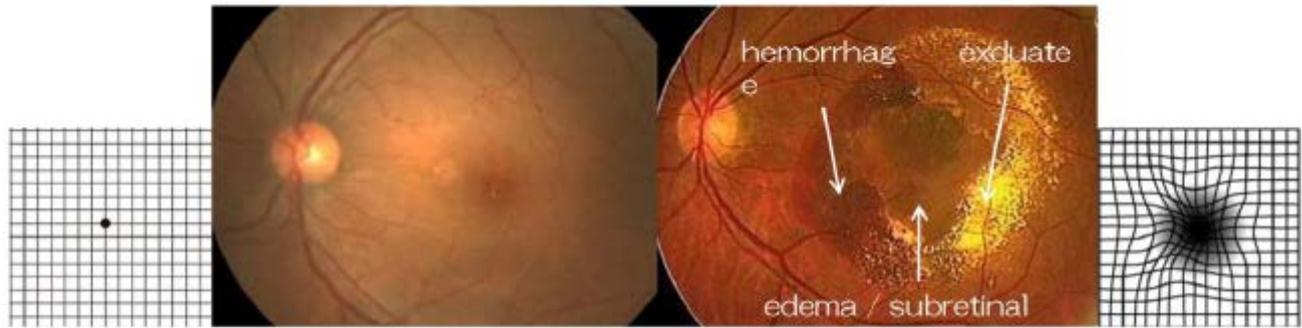
Age-related macular degeneration

- Japan: No.4 cause of blindness. Affects about 1% of people aged 50 and over. Increase with advancing age
- U.S. and Europe: No.1 cause of blindness



Normal

AMD



Current therapy (anti-VEGF antibody)

-> No improvement in 40 % of patients
No curative treatment

- ✓ Denaturation atrophy detachment RPE cell
=> Nutrition to retina, digestion of waste, depression of barrier ability
- ✓ Accumulation of waste
- ✓ Occurrence of choroidal neovascular

Regenerate retinal pigment epithelial (transplant)

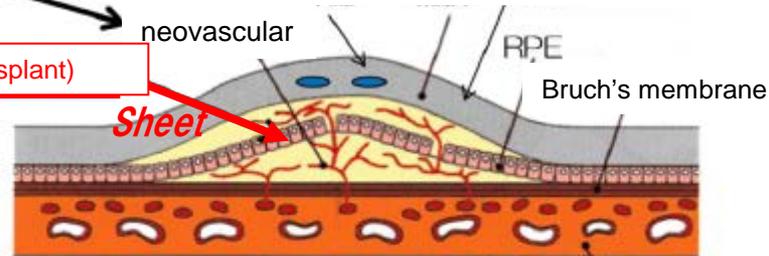
Suspension

drusen



dry type AMD

Sheet



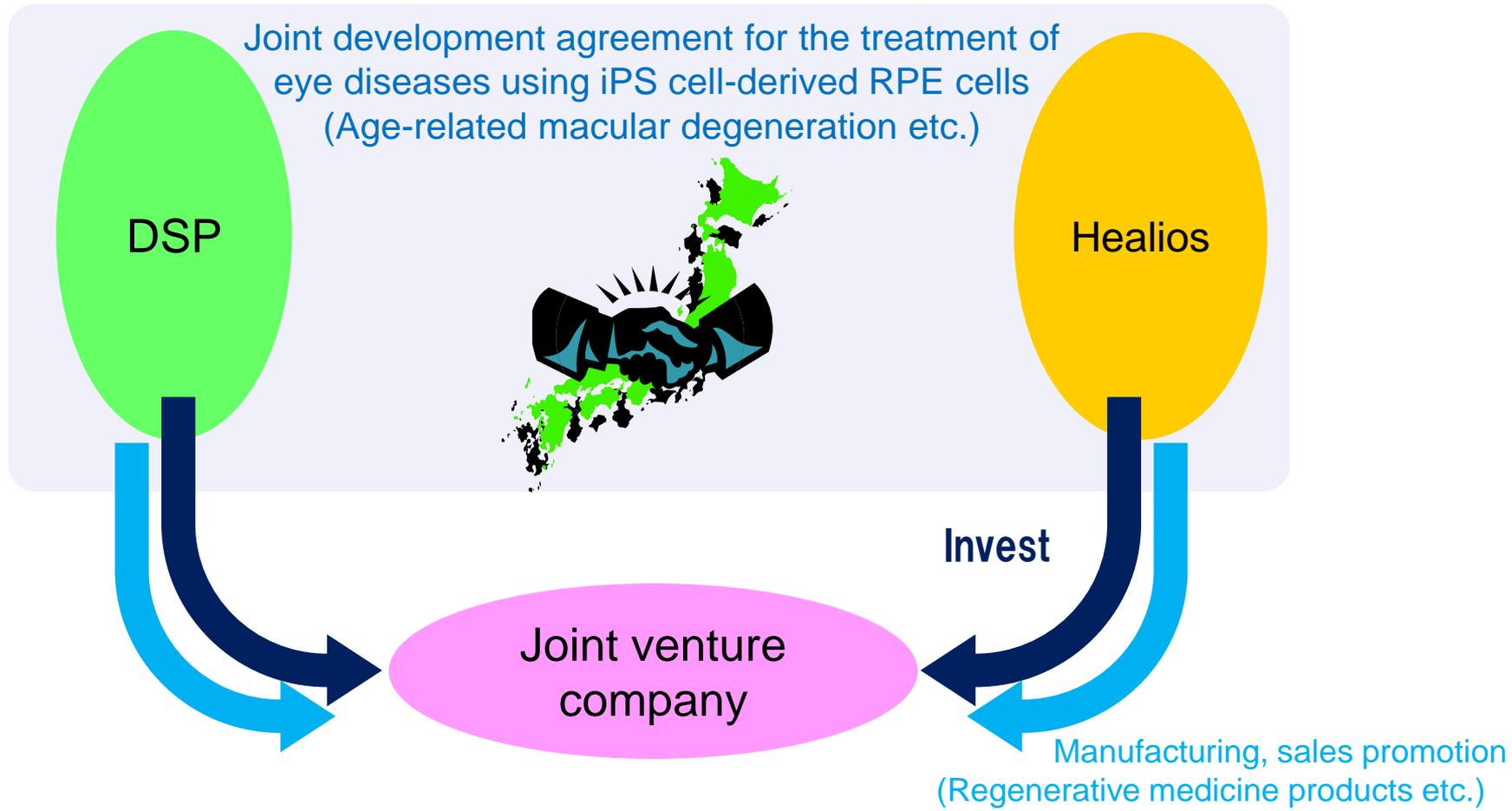
wet type AMD

choroid

No care for dry type

Wet type is major in Japan

Outline of alliance



Manufacturing, sale, export, import and other activities of pharmaceuticals, medical equipment, regenerative medicine products, etc. in the field of eye diseases

Alliance 1 - Joint development agreement -

[Scope]

- ◆ Products : iPS cell-derived RPE cells products (sheet or suspension)
- ◆ Indications: Eye diseases / Wet AMD, Dry AMD, others
To be determined by Joint-development committee

[Sharing roles]

Healios	DSP
➤ Joint development committee: joint development policy, assigning tasks, decision making	
<ul style="list-style-type: none">➤ Examination of the quality and the stability of RPE➤ Non-clinical and clinical trials➤ Manufacturing products for trials➤ Post-marketing clinical studies➤ Obtain and maintain manufacturing and marketing approval	<ul style="list-style-type: none">➤ Review of documents before submitting to authorities➤ Evaluation of trial findings

[Development costs] DSP cover maximum 5,200 million yen

[Manufacturing, sales promotion] Contracted exclusively to the joint venture company

[Post-marketing clinical study required for approval] Contracted to DSP from Healios

Alliance 2 - Joint venture agreement -

[Purpose]

- ◆ Healios and DSP jointly establish a company
- ◆ The joint venture company acts as a contract manufacturing and sales organization for pharmaceuticals, medical equipment, regenerative medicine products in the field of eye diseases

[Date of establishment] February, 2014 (planned)

[Business scope] Manufacturing and sale and other activities of pharmaceuticals, medical equipment, regeneration medicine products and other products in the field of eye diseases

[Capital etc.]

- ◆ Paid-in capital: 50 million yen (+ capital reserve of 50 million yen)
- ◆ Shareholding : 50:50

[Directors]

- ◆ Directors: 4 persons
- ◆ Representative director: 1 person (president). For 6 years after establishment (Two 3-year terms) -- Hardy T S Kagimoto, MD

The joint venture company will manufacture and promote the products under the license from Healios and DSP to use the outcomes of the joint development program.

Alliance 3 - License agreement -

[Contents]

- ◆ All the technologies patents, know-hows, etc. of Healios related to RPE cells are licensed to DSP



[Healios]

- ◆ Healios receives a down payment of 500 million yen
- ◆ Healios receives total development milestone payments of 1,100 million yen

[DSP]

- ◆ DSP receives exclusive license to RPE cell products for Japan and non-exclusive license to other products for worldwide territories from Healios
- ◆ DSP strengthen its activities in the field of regenerative medicine / cell therapy

Purpose of Alliance: Healios

- ◆ Construct a framework of manufacturing and marketing approvals of first-in-the-world iPS cell pipelines
- ◆ Complete value chain by own approvals
- ◆ The further substantial iPS pipeline except for a field of eye diseases as the base of this alliance
- ◆ Create a new global industry

Manufacturing and sales approval system in the global market

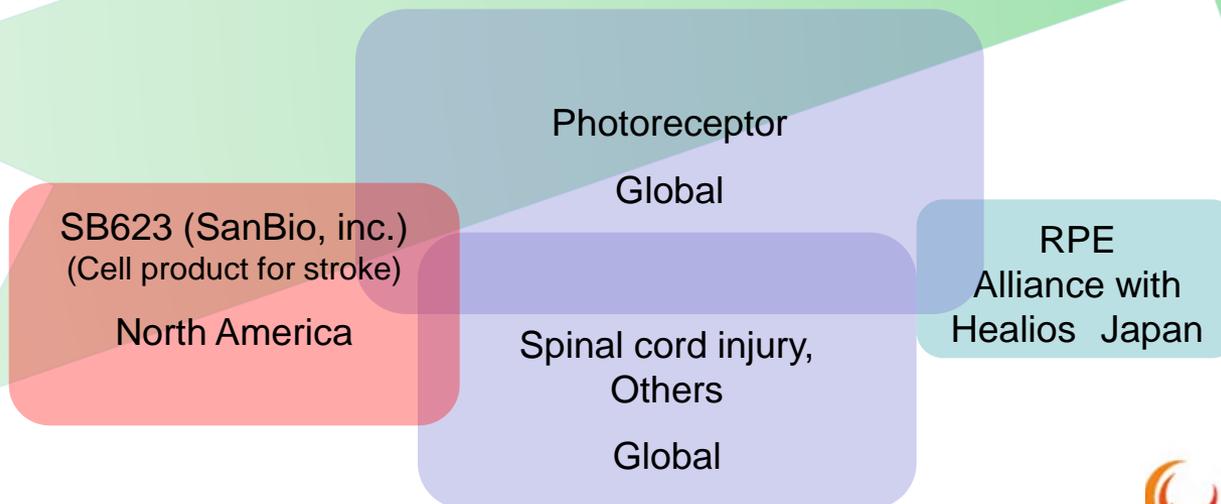
Establish the foundation centered on iPS cells by construction a framework of manufacturing and marketing approvals in Japan

December 2, 2013

Alliance with DSP for Japanese market

Purpose of Alliance: DSP

- ◆ Start world's first regenerative medicine business based on iPS cells
 - Launch regenerative medicine business based on iPS cells
 - Build business base in a field of eye diseases
 - Establish business base in-house to develop, manufacture and set standards of regenerative and cell medicine products
 - Expand regenerative medicine business globally with utilizing patents and know-hows which are licensed from Healios
- ◆ First step to become a leading company in regenerative medicine and cell therapy based on iPS cells etc.



Healios and DSP 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.

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Actual financial results may differ materially from those presented in this document, being dependent on a number of factors.

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