

February 10, 2026

RAYMEI Inc.

## Announcement regarding the launch of a clinical trial of allogeneic iPS cell-derived corneal epithelial cell sheets

- Aiming for practical application of the new treatment for limbal stem cell deficiency -

RAYMEI Inc. (President: Masakazu Kobayashi; Headquarters: Kita-ku, Osaka-shi, Osaka; hereinafter referred to as “RAYMEI”) announced its launch of a company-sponsored clinical trial of allogeneic iPS cell-derived corneal epithelial cell sheets (Development code: REM-01) in patients with limbal stem cell deficiency.

Corneal transplantation is a key treatment option for serious corneal diseases. However, due to the shortage of donated corneal tissue, which remains a challenge, some patients cannot receive adequate treatment. To resolve this issue, RAYMEI will strive to put the new treatment using regenerative medicine into practical use.

### 1. Launch of the company-sponsored clinical trial to market authorization

RAYMEI has been working towards the clinical application of the corneal epithelial cell sheets based on the study findings of the self-formed ectodermal autonomous multi-zone (SEAM) method, which was developed by the Department of Ophthalmology and Department of Neural and Sensory Organ Surgery of the University of Osaka Graduate School of Medicine led by Professor Kohji Nishida.

The Pharmaceuticals and Medical Devices Agency (PMDA) has now completed the review before commencement of the clinical trial (30-day Clinical Trial Notification review) and we are ready to start the company-sponsored clinical trial of REM-01.

### 2. Overview of the clinical trial

This clinical trial is conducted to evaluate the efficacy and safety of REM-01 in patients with limbal stem cell deficiency.

- Investigational product: Allogeneic iPS cell-derived corneal epithelial cell sheets (Development code: REM-01)
- Target disease: Limbal stem cell deficiency
- Investigational sites: A total of 6 institutions including the University of Osaka Hospital
- Target sample size: 12 subjects
- Scheduled first transplantation: Spring 2026
- Scheduled completion of the clinical trial: December 2027
- Upcoming schedule: The application for marketing authorization will be submitted after completing the clinical trial.

### 3. For production and sales of corneal epithelial cell sheets (Enhancement of collaboration with Rohto Pharmaceutical Co., Ltd.)

Following the launch of the company-sponsored clinical trial, RAYMEI will receive additional funding from Rohto Pharmaceutical Co., Ltd. (President and Representative Director: Hidetoshi Segi; Headquarters: Ikuno-ku, Osaka-shi, Osaka; hereinafter referred to as “Rohto Pharmaceutical”) to

further strengthen their collaboration aimed at promoting the practical application of regenerative medicine in the field of ophthalmology.

By establishing a system to ensure stable supply of allogeneic iPS cell-derived corneal epithelial cell sheets, we will work together with Rohto Pharmaceutical to create an environment where treatment is provided to patients in need of corneal transplantation who lack access to adequate treatment and to provide new therapeutic options.

#### 4. Definition of terms

##### ■ Limbal stem cell deficiency

A disorder caused by the loss or functional impairment of corneal epithelial stem cells that are essential to maintain the corneal epithelium, which leads to the loss of corneal transparency, reduced vision, and ocular pain.

##### ■ SEAM method

A technique to induce simultaneous generation of the parts of the eye in the anterior segment (cornea, lens, etc.) and posterior segment (retina, retinal pigment epithelium, etc.) from iPS cells.

#### 5. Company Profile

RAYMEI Inc.

Name	RAYMEI Inc.
Representative	Masakazu Kobayashi
Headquarters	Osaka Ekimae Building No. 3 30F, 1-1-3 Umeda, Kita-ku, Osaka-shi, Osaka 530-0001, Japan
Business overview	Research and development and marketing of regenerative medical products and cell therapies

Rohto Pharmaceutical Co., Ltd.

Name	Rohto Pharmaceutical Co., Ltd.
Representative	Hidetoshi Segi
Headquarters	1-8-1, Tatsumi-nishi, Ikuno-ku, Osaka-shi, Osaka 544-8666, Japan
Business overview	Production and sales of pharmaceuticals, cosmetics, and functional foods

[Contact information]

RAYMEI Inc.

Web <https://www.raymei.co.jp/>

E-mail [info@raymei.co.jp](mailto:info@raymei.co.jp)