

July 10, 2026
RAYMEI Inc.

Announcement regarding the first patient treatment in a clinical trial of allogeneic iPS cell-derived corneal epithelial cell sheets

- Allogeneic iPS cell-derived corneal epithelial cell sheet (REM-01) transplantation in a single-arm unmasked Phase-2 clinical trial in patients with limbal stem cell deficiency -

RAYMEI Inc. (President: Masakazu Kobayashi; Headquarters: Kita-ku, Osaka-shi, Osaka; hereinafter referred to as “RAYMEI”) announced that it has conducted the first patient transplantation in a single-arm unmasked Phase-2 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 treatment option for serious corneal diseases. However, some patients cannot receive adequate treatment due to lack of corneal tissue donors, which remains a challenge. To resolve this issue, RAYMEI has been working toward the clinical application of allogeneic iPS cell-derived corneal epithelial cell sheets based on 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 Koji Nishida).

On July 9, 2026, REM-01 transplantation was conducted for a patient with limbal stem cell deficiency at the University of Osaka Hospital as the first case of the company-sponsored clinical trial. To ensure patient safety, the patient will be discharged from the hospital after undergoing tests and thereafter be followed up on an outpatient basis.

The transplantation will be conducted for the second and subsequent patients at the hospital and other investigational sites.

1. 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

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- First transplantation: July 2026
- Scheduled completion of the clinical trial: December 2027

2. Schedule for the conduct of the clinical trial and market authorization

After the conduct of transplantation for the first subject in July 2026 and completion of transplantation for all subjects by December of the same year, the application for marketing authorization will be submitted with one-year follow-up data in 2028.

3. 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.

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