

June 20, 2025

To whom it may concern:

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Announcement of completion of subject dosing in global Phase III clinical trial of “K-321,” a treatment for Fuchs endothelial corneal dystrophy

We hereby announce that we have received a notice from Kowa Company, Ltd. (“Kowa”), our licensee, that subject dosing has been completed in the global phase III clinical trial (“the trial”) of the ophthalmic solution “K-321” (“the product”), which contains ripasudil hydrochloride hydrate, a Rho kinase ^(Note 1) inhibitor discovered initially by our company.

The trial is being conducted in multiple countries and regions, including the United States and Europe, targeting patients with Fuchs endothelial corneal dystrophy. It aims to evaluate the efficacy and safety of the product administered as an eye drop after Descemet’s membrane stripping surgery in comparison with a placebo. Currently, the trial is in the follow-up observation period under double-masked conditions ^(Note 2), and observation of all subjects is scheduled to be completed by the end of March 2026.

As a result, subject dosing in both ongoing global phase III clinical trials has now been completed, together with the announcement dated March 18, 2025, titled “Announcement of completion of subject dosing in global phase III clinical trial of ‘K-321,’ a treatment for Fuchs endothelial corneal dystrophy.”

Fuchs endothelial corneal dystrophy causes damage to the corneal endothelium as the disease progresses. The development of effective therapeutic agents is eagerly awaited, as corneal transplantation is currently the main option for corneal endothelial damage with severe visual impairment. We and Kowa will continue to develop “K-321” to provide patients with new treatment options.

Due to this matter, there will be no change to the earnings forecast for the fiscal year ending December 2025.

Ripasudil hydrochloride hydrate

Kowa began marketing GLANATEC® Ophthalmic Solution 0.4%, which contains ripasudil hydrochloride hydrate as the active ingredient, in Japan in December

2014. As a Rho kinase inhibitor, ripasudil hydrochloride hydrate has shown potential to act on kinases in the eye, with the possibility that indications could be expanded to include other ophthalmic diseases. Kowa is undertaking the clinical study on K-321 with a view to obtaining approval for the indication of Fuchs endothelial corneal dystrophy.

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Explanation of terms

(Note 1) Rho kinase (ROCK: Rho-associated, coiled-coil containing protein kinase)
Rho kinase is one of the protein phosphorylation enzymes (protein kinase). This enzyme is involved in the regulation mechanism of versatile cell responses based on the Rho-ROCK information transmission.

(Note 2) Double-masked conditions.

This refers to a condition in which neither the subjects nor the evaluating physicians know whether K-321 or a placebo has been administered.