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To whom it may concern:

Company	D. Western Therapeutics Institute, Inc.
Representative	Yuichi Hidaka, President and CEO
	(Code No. 4576)
Contact	Sayako Matsubara, Director
TEL	052-218-8785

Announcement regarding completion of the observation period for subjects in the global phase III clinical study of “K-321,” a treatment for Fuchs endothelial corneal dystrophy

With respect to K-321 (hereinafter the “Drug”), an ophthalmic solution whose active ingredient is the Rho kinase (Note) inhibitor ripasudil hydrochloride hydrate that we discovered, we hereby announce that we have received a notice from Kowa Company, Ltd., our licensee (hereinafter “Kowa”), that the observation period for subjects has been completed in the earlier of the two global phase III clinical studies (hereinafter the “Study”).

Two global phase III clinical studies of the Drug are currently in progress. The Study in which the observation period for all subjects has now been completed is the clinical study that we announced in the timely disclosure dated March 18, 2025, titled “Announcement regarding completion of administration to subjects in the global phase III clinical study of ‘K-321,’ a treatment for Fuchs endothelial corneal dystrophy.”
The Study is intended to evaluate, in patients with Fuchs endothelial corneal dystrophy, the efficacy and safety of the Drug compared with placebo when the Drug is administered as an ophthalmic solution after simultaneous Descemet’s membrane stripping and cataract surgery.
Going forward, data from the subjects will be collected and analyzed statistically. We will promptly announce the results once they are available.

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) 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.