PRESS RELEASE

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Dear all

Kowa Company, Ltd.

Initiation of Phase 3 clinical study in the United States Indication for Fuchs endothelial corneal dystrophy [Development code: K-321]

Kowa Company, Ltd. (hereafter referred to as "Kowa") has been developing "Ripasudil Hydrochloride Dihydrate" (hereafter referred to as "this Substance"), a Rho kinase inhibitor, for the indication of Fuchs endothelial corneal dystrophy (FECD) (Development code: K-321).

The Phase 2 study of K-321 in this development program investigated the efficacy and safety of K-321 ophthalmic solution for 12 weeks treatment, in patients with FECD after descemetorhexis, compared to placebo. Based upon the results of this Phase 2 study, Kowa decided to initiate a Phase 3 study.

This Substance was launched in December 2014 in Japan (Brand name: GLANATEC® ophthalmic solution 0.4%) as the world's first glaucoma drug with Rho kinase inhibitory activity, and it was approved in Korea, Singapore, Malaysia, and Thailand in February 2019, February 2020, July 2020, and August 2020, respectively. Because this Substance has Rho kinase inhibitory activity, Kowa has been considering potential therapeutic use in other ophthalmic diseases in addition to glaucoma.

■GLANATEC® Ophthalmic Solution 0.4%

GLANATEC® Ophthalmic Solution 0.4% includes this Substance, which was licensed from D. Western Therapeutics Institute, Inc. (DWTI) to Kowa, as an active ingredient, and lowers intraocular pressure by promoting discharge of aqueous humor through a main outflow via trabecular meshwork-Schlemm

canal as a result of Rho kinase inhibition.

■Fuchs endothelial corneal dystrophy (FECD)

Fuchs corneal endothelial dystrophy leads to corneal endothelial damage as the symptoms progress, and corneal transplantation is the only option for corneal endothelial damage with severe visual impairment, and development of effective therapeutic drugs is desired.