PRESS RELEASE

April 6, 2023

Dear all

Kowa Company, Ltd.

Initiation of a new Phase 3 global clinical study for the Indication of 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).

Following the trial announced on March 22, Kowa today announced that a new Phase 3 global clinical study was initiated to evaluate the efficacy and safety of K-321 ophthalmic solution in patients with FECD after simultaneous cataract surgery and descemetorhexis compared to placebo.

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 investigating potential therapeutic use in other ophthalmic diseases in addition to glaucoma.

■GLANATEC® Ophthalmic Solution 0.4%

GLANATEC® Ophthalmic Solution 0.4% includes this Substance 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)

FECD leads to corneal endothelial damage as the symptoms progress, and corneal transplantation has been the only option to treat corneal endothelial damage with severe visual impairment, and development of effective therapeutic drugs is desired.