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Kowa Announces the Efficacy and Safety of a Novel Rho Kinase Inhibitor (K-115) in the Treatment of Glaucoma

—The Association for Research in Vision and Ophthalmology (ARVO) 2011—

Tokyo, Japan, May 09, 2011--- Kowa Company Ltd, (Headquarters: Nagoya, Japan, President & CEO: Yoshihiro Miwa, “Kowa”) today announced the results of a Phase 2 clinical pharmacology study, a Phase 2 dose-response study and a non-clinical study of a drug candidate for glaucoma and ocular hypertension (K-115) which is being developed in Japan. The results were presented as three posters at The Association for Research in Vision and Ophthalmology (ARVO) 2011 meeting in Fort Lauderdale, Florida, USA. The results of the two clinical studies can be read as an E-poster on the ARVO 2011 website during and after the conference.

K-115 lowers intraocular pressure (IOP) by increasing conventional aqueous outflow. Consequently, additive effects are anticipated when K-115 is used in combination with other anti-glaucoma drugs. K-115 will also be developed as monotherapy for glaucoma.

Based on the results of these Phase 2 studies, Kowa will continue its clinical development program in Japan and will initiate Phase 3 studies with the aim of achieving marketing authorization as the world’s first Rho kinase inhibitor for the treatment of glaucoma and ocular hypertension.
Presentations accepted by ARVO 2011 are as follows:

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*E-Poster can be browsed for 24 hours via ARVO2011 Online E-Poster Viewer System from May 01 to June 30, 2011


ARVO 2011

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Glaucoma and ocular hypertension

Glaucoma is a leading cause of blindness in Japan. If glaucoma patients are not treated appropriately and their IOP remains high, optic nerve damage results, leading to a progressively narrowed visual field and eventually blindness. Ocular hypertension is a condition in which intraocular pressure is higher than normal in the absence of visual field loss. According to a detailed epidemiologic investigation, from the year 2000 to 2001 in Japan, the prevalence of glaucoma in adults over forty years of age is 5.0%, and about eighty percent of them have primary open angle glaucoma (POAG).

Lowering IOP is the only robust choice to treat glaucoma based on the evidence at present. Drug therapy is considered to be the first choice to treat POAG.
Mechanism of Rho kinase inhibition

K-115, a Rho kinase inhibitor, reduces IOP by direct action on the trabecular meshwork, thereby increasing conventional outflow through the trabecular meshwork-Schlemm's canal which is considered to be the main pathway of outflow of aqueous fluid. K-115's mechanism of action, which is unlike some other anti-glaucoma agents, may offer additive effects in the treatment of glaucoma when used in combination with other clinically available agents, such as prostaglandin analogues which increase uveoscleral outflow and β blockers which reduce aqueous production.

About Phase 2 clinical pharmacology study (Poster : A512)

28 patients with POAG or ocular hypertension were administered K-115 (0.2%, 0.4% or placebo) twice for one day to investigate the time course of IOP reduction over 24 hours and to estimate a clinically recommended dose.

About Phase 2 dose-response study (Poster : A516)

210 patients with POAG or ocular hypertension were administered twice daily K-115 (0.2%, 0.4% or placebo) for 8 weeks to investigate the dose-response of IOP reduction and the safety of K-115. K-115 induced a dose-dependent reduction in IOP, and all concentrations of K-115 exhibited acceptable tolerability profiles. In addition, it was confirmed that IOP could be controlled over 24 hours with twice daily dosing of K-115.

About the non-clinical studies (Poster : A533)

In one study, IOP reduction was investigated in monkeys following administration of K-115 in combination with latanoprost (a prostaglandin analogue). An additive effect on IOP reduction was confirmed. In additional studies, the effects of K-115 on aqueous production and outflow were investigated, and the intraocular distribution of K-115 in rabbits was confirmed. Furthermore, Rho kinase expression in the ocular tissues of monkeys and rabbits was confirmed.

About Kowa

Kowa has made intraocular and lifestyle disease R&D priorities, and is endeavoring
to develop and explore innovative medicines. In addition, Kowa focuses on three major activities: drug discovery, innovative formulation discovery, and the development of neo generics, and actively engages in R&D activities to satisfy unmet medical needs.

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