

News release

Kyowa Kirin Announces Approval of Topical Ophthalmic Mitomycin C Agent in Japan

Tokyo, Japan, December 26, 2022 --Kyowa Kirin Co., Ltd. (TSE:4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces that mitomycin C agent (MITOMYCIN 2mg for Ophthalmic Topical Use), licensed from Intas Pharmaceuticals Ltd. ("Intas") was approved by Ministry of Health, Labour and Welfare ("MHLW") for "an adjunct to open glaucoma surgery" in Japan.

The Japanese Ophthalmological Society has requested that the anticancer agents, mitomycin C, which are marketed by Kyowa Kirin in Japan, can be used during surgery for glaucoma with ocular hypertension. Additionally, MHLW reported its opinion that mitomycin C meets the "criteria for medical necessity" at the "Review Committee on Unapproved or Off-label Drugs with High Medical Need" held on May 29, 2019. Kyowa Kirin later received a request for development for this indication from MHLW.

This approval is based on the application that Kyowa Kirin filed in January 2022 for manufacturing and marketing approval of mitomycin C agent, as a topical ophthalmic agent which is licensed from Intas for the Japanese market.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

About Intas Pharmaceuticals Ltd.

Intas Pharmaceuticals Ltd. is a leading vertically integrated pharmaceutical company based in Ahmedabad, India, having end-to-end capabilities of formulation development, manufacturing and marketing along with backward integration of APIs. Intas has more than 16,000 employees, sells products in more than 85 countries and has 14 manufacturing sites worldwide. The Intas group's revenues amounted to USD 2.1 bn in FY 2020-21 and the

compounded annual growth rate of Intas' revenues has exceeded 25% in the past 10 years. For more information, please visit www.intaspharma.com

About Open Surgery for Glaucoma

Glaucoma causes characteristic changes in the optic nerve and visual field and is the leading cause of blindness in Japan. Treatment to lower intraocular pressure (IOP) is usually performed, and there are several treatment options for lowering IOP in glaucoma, including drug therapy, laser therapy, and surgery. Fibrolysis, the most common of these surgeries, is described in domestic and international guidelines as an intraoperative use of mitomycin C, which inhibits fibroblast proliferation, to prevent scarring at the filtration site (J Ophthalmol 2022; 126: 85-177, Ophthalmology 2020; 128: 71-150, Terminology and guidelines for glaucoma, 5th edition. European Glaucoma Society; 2020). However, no drug had been approved for this use in Japan.