

News release

Kyowa Kirin Announces NDA Submission of Topical Ophthalmic Mitomycin C Agent in Japan

Tokyo, Japan, January 31, 2022 --Kyowa Kirin Co., Ltd. (TSE:4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces that the company has submitted an NDA (New Drug Application) to the Ministry of Health, Labour and Welfare ("MHLW") for manufacturing and marketing approval of mitomycin C, licensed from Intas Pharmaceuticals Ltd. ("Intas") as a topical ophthalmic drug for use in glaucoma surgery in Japan.

The Japanese Ophthalmological Society has requested that the anticancer agents "Mitomycin for injection 2mg" and "mitomycin for injection 10mg," which are marketed by Kyowa Kirin in Japan, can be used during surgery for glaucoma and ocular hypertension. Additionally, at the "Review Committee on Unapproved or Off-Label Drugs with High Medical Needs" held on May 29, 2019, the opinion that the drug meets the "criteria for medical necessity" was reported. Kyowa Kirin later received a request for development for this indication from the MHLW and submitted its opinion on the appropriateness of filing a public knowledge-based application. In the meantime, Kyowa Kirin has been recalling the products since October 2019 due to the discovery of facts that could affect the assurance of sterility in the manufacturing process of the active pharmaceutical ingredients of both drugs. Since it was discovered that it would take a considerable amount of time to resume manufacturing of the two drugs, we are currently unable to provide a specific date for resumption of supply.

Kyowa Kirin has investigated the domestic supply of mitomycin C and concluded to introduce the formulation of mitomycin C for topical ophthalmic use from Intas for the Japanese market and has submitted the NDA for manufacturing and marketing approval in Japan.

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 <https://www.intaspharma.com/>