

# News release

## **Kyowa Kirin Received Partial Change Approval of Antineoplastic Mitomycin C Agent in Japan**

Tokyo, Japan, June 23, 2023 --Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that the company has received approval from the Ministry of Health, Labour and Welfare (“MHLW”) for partial change of its antineoplastic mitomycin C agents (Mitomycin Injection 2 mg and Mitomycin Injection 10 mg) for the purpose of changing to a manufactured product in-licensed from Intas Pharmaceuticals Ltd. (Intas).

Kyowa Kirin voluntarily recalled its mitomycin C agent from October 2019 due to the discovery of facts that could affect the assurance of sterility in the API manufacturing process. Since then, Kyowa Kirin has been taking all possible actions to resume the supply of this product. In September 2022, Kyowa Kirin submitted an application to seek approval of Intas-licensed mitomycin C agent for use as an antineoplastic agent in Japan. Currently, the supply is under preparation and will be started when it is ready.

Apart from above, the topical ophthalmic mitomycin C agent (MITOMYCIN 2 mg for Ophthalmic Topical Use) had been approved by MHLW on December 23, 2022 and has been listed on the NHI (National Health Insurance) drug price list on May 24, 2023. Currently Kyowa Kirin is making preparation for its launch.

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 19,000 employees, sells products in more than 85 countries and has 14 manufacturing sites worldwide. The Intas group's revenues amounted to USD 2.5 bn in FY 2021-22 and the compounded annual growth rate of Intas' revenues has exceeded 20% in the past 10 years.

For more information, please visit [www.intaspharma.com](http://www.intaspharma.com)