

News release

Kyowa Kirin Filed Partial Change Application of Antineoplastic Mitomycin C Agent in Japan

Tokyo, Japan, October 17, 2022 --Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that the company has filed an application for partial change of approved indication for its antineoplastic Mitomycin C agent (Mitomycin Injection 2mg and Mitomycin Injection 10mg), which is licensed from Intas Pharmaceuticals Ltd. (Intas), in Japan.

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. Following the NDA filing for topical ophthalmic use early this year in January, Kyowa Kirin also submitted an application to seek approval of Intas-licensed mitomycin C agent for use as an antineoplastic agent in Japan. To file this application, some of the current approval indications and routes of administration were changed.

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 2.5 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