

## **Kyowa Kirin Announces NDA Submission of Automated Injection Device of G-Lasta<sup>®</sup> in Japan**

**Tokyo, Japan, September 1, 2021** --Kyowa Kirin Co., Ltd. (TSE:4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces that it submitted an NDA (New Drug Application) of automated injection device of G-Lasta<sup>®</sup> [KRN125, generic name: pegfilgrastim (genetical recombination), long-acting Granulocyte Colony-Stimulating Factor<sup>\*1</sup> (G-CSF) preparation], which has been co-developed with Terumo Corporation (TSE:4543, "Terumo"), for decreasing the incidence of febrile neutropenia<sup>\*2</sup> in patients receiving cancer chemotherapy on August 30th in Japan.

G-Lasta is a long-acting G-CSF preparation, which has been licensed from Kirin-Amgen Inc. to Kyowa Kirin. It has been marketed in Japan since 2014 indicated for the treatment of decreasing the incidence of febrile neutropenia in patients receiving cancer chemotherapy. It is typically administered by medical staff at least one day after chemotherapy. This automated injection device has a function to deliver G-Lasta into the body on the next day of chemotherapy. With applying it to patients on the same day of chemotherapy, an outpatient visit required for administration of G-Lasta on the following day can be omitted. With the device, it is expected that burden on both patients and healthcare professionals can be reduced.

"We are delighted with the NDA submission for the automated injection device of G-Lasta, for which we are confident that it will contribute to reducing burden on patients and caregivers," said Tomohiro Sudo, Executive Officer, Head of Global Product Strategy Department at Kyowa Kirin. "Working closely with Terumo, we will continue to strive to deliver this new device to patients."

This application is based on the result of safety data from the phase 1 clinical study conducted by Kyowa Kirin.

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.

**\*1: About Granulocyte Colony-Stimulating Factor (G-CSF)**

G-CSF is a protein produced by gene recombination technology. G-CSF selectively stimulates production of neutrophils and also enhances the neutrophil function. Based on this mechanism, G-CSF accelerates recovery from chemotherapy-induced neutropenia and reduces various risks associated with neutropenia.

**\*2: About febrile neutropenia**

Myelosuppressive chemotherapy causes low neutrophil count, i.e. neutropenia, which can raise risk of infections. Neutropenia with fever, known as febrile neutropenia, can be a sign of a serious infection and patients' needs to be given appropriate treatments.