KYOWA KIRIN

News release

Kyowa Kirin Announces Launch of "G-Lasta® Subcutaneous Injection 3.6 mg BodyPod" in Japan

- *New treatment option to reduce the burden of visit to clinic for patients undergoing chemotherapy by automatically injecting G-Lasta® to patients with the Product*

Tokyo, Japan, December 6, 2022 --Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") today announced that G-Lasta® Subcutaneous Injection 3.6 mg BodyPod ("the Product"), which is an automated injection device of G-Lasta® [KRN125, generic name: pegfilgrastim (genetical recombination), long-acting Granulocyte Colony-Stimulating Factor*1 (G-CSF) preparation], is to be launched in Japan today for decreasing the incidence of febrile neutropenia*2 in patients receiving cancer chemotherapy.

G-Lasta® is a long-acting G-CSF preparation, which has been licensed from Amgen K-A, Inc. to Kyowa Kirin. It has been marketed in Japan since 2014 with the indication 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 works by delivering a dose of G-Lasta® into the body approximately 27 hours after it is attached to the patient. By attaching it to patients on the day of chemotherapy, an additional outpatient visit required for administration of G-Lasta® on the following day can be omitted. Kyowa Kirin thinks that burden on patients undergoing chemotherapy can be reduced with the Product.

"We are very pleased with the launch of G-Lasta® Subcutaneous Injection 3.6 mg BodyPod. We would like to express our sincere appreciation to all those who cooperated in the development of the product and to Terumo Corporation who worked with us closely," said Tomohiro Sudo, Executive Officer, Head of Global Product Strategy Department at Kyowa Kirin. "We will continue our activities to bring the new value of this product to patients, caregivers, and medical staff who are involved in cancer chemotherapy."

The Product had been co-developed with Terumo Corporation (TSE:4543). Kyowa Kirin submitted the NDA of the Product based on safety data from the phase 1 clinical study and it was approved in July 2022. It was listed on the National Health Insurance (NHI) pricing list in November 2022.

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.