News release

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

- *Expected to reduce the burden on the patient to return to the clinic the next day after chemotherapy by providing G-Lasta® to patients automatically with the product*

Tokyo, Japan, August 1, 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], was approved by Japan's Ministry of Health, Labour and Welfare (MHLW) for decreasing the incidence of febrile neutropenia*2 in patients receiving cancer chemotherapy on July 28.

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 one day 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. With the product, it is expected that burden on both patients and medical staff can be reduced.

"We are very pleased with the approval of G-Lasta® Subcutaneous Injection 3.6 mg BodyPod. We believe the product will deliver new value to patients, caregivers, and medical staff who are involved in cancer chemotherapy," said Tomohiro Sudo, Executive Officer, Head of Global Product Strategy Department at Kyowa Kirin. "We will continue to make further effort to launch the product with Terumo Corporation."

The product had been co-developed with Terumo Corporation (TSE:4543) . Kyowa Kirin submitted the NDA of the product based on the result of safety data from the phase 1 clinical study conducted by Kyowa Kirin in August 2021.

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.