Kyowa Kirin Announces Application for Partial Change of Approved Indication of G-Lasta® for the Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation in Japan

Tokyo, Japan, July 24, 2023 --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 of the sustained duration form of G-CSF(Granulocyte-Colony Stimulating Factor)[*1] product G-Lasta® [KRN125, generic name: pegfilgrastim (genetical recombination)] for the mobilization of hematopoietic stem cells into peripheral blood in autologous blood stem cell transplantation[*2] (the "indication") in Japan today.

This application is based on the results of a clinical trial conducted by Kyowa Kirin to evaluate the effect of G-Lasta on the mobilization of hematopoietic stem cells into peripheral blood in patients with multiple myeloma and malignant lymphoma.

G-Lasta is a long-acting G-CSF preparation licensed from Amgen K-A and has been marketed in Japan since 2014 for decreasing the incidence of febrile neutropenia[*3] in patients receiving cancer chemotherapy. In February 2022, Kyowa Kirin received an approval for the indication of G-Lasta for the mobilization of hematopoietic stem cells into peripheral blood in allogeneic blood stem cell transplantation[*4]. By adding the indication of this sustained duration preparation to autologous blood stem cell transplantation, Kyowa Kirin expects to contribute to reducing burden on patients in hematopoietic stem cell transplantation therapy.

“We are very delighted with this application to add the indication to autologous blood stem cell transplantation therapy,” said Yuichi Kawasaki, Executive Officer, Director of Product Strategy Department of Strategy Division at Kyowa Kirin. “We will continue to strive to deliver this product to patients and provide new value to the blood stem cell transplantation therapy area.”

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 stimulates production of neutrophils, which may be reduced due to chemotherapy, and reduces the risk of febrile neutropenia. It also mobilizes of hematopoietic stem cells into peripheral blood.

***2: About mobilization of hematopoietic stem cells into peripheral blood for autologous blood stem cell transplantation**

Autologous peripheral blood stem cell transplantation is one of the treatments for multiple myeloma and malignant lymphoma. In contrast to allogeneic transplantation, it transplants hematopoietic stem cells harvested from the patients themselves in this treatment. Daily-dose G-CSF products are widely used to mobilize hematopoietic stem cells into peripheral blood. It is common to conduct an apheresis (separation and collection of blood cell components) using a blood component separator after mobilization of hematopoietic stem cells into peripheral blood by any of the following three methods: only G-CSF products, G-CSF products plus plerixafor (inhibitor of CXCR4 receptor, one of the Chemokine Receptor), or G-CSF products plus chemotherapy.

***3: About febrile neutropenia**

Myelosuppressive chemotherapy may cause 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. Prophylactic G-CSF therapy is recommended for patients receiving chemotherapies that are known to elevate the risk of febrile neutropenia.

***4: About mobilization of hematopoietic stem cells into peripheral blood for allogeneic blood stem cell transplantation**

Allogeneic peripheral blood stem cell transplantation is one of the treatments for malignancies such as leukemia, as well as non-neoplastic blood diseases such as aplastic anemia. In order to harvest hematopoietic stem cells for transplantation into recipients from donors, daily-dose G-CSF products are widely used to mobilize hematopoietic stem cells into peripheral blood. In the case of daily G-CSF products, they are commonly administered subcutaneously once or twice daily and followed by apheresis (separation and collection of blood cell components) using a blood component separator on 4th to 6th day.