

# News release

## **Kyowa Kirin Announces Approval for Partial Change of Approved Indication of G-Lasta<sup>®</sup> for the Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Allogeneic Blood Stem Cell Transplantation in Japan**

**Tokyo, Japan, February 25, 2022** --Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that the company received an approval for partial change of approved indication of G-Lasta<sup>®</sup> [KRN125, generic name: pegfilgrastim (genetical recombination), long-acting Granulocyte Colony-Stimulating Factor<sup>\*1</sup> (G-CSF) preparation] according to the additional indication, dosage, and administration for the mobilization of hematopoietic stem cells into peripheral blood in allogeneic blood stem cell transplantation<sup>\*2</sup> in Japan.

This approval is based on the results of the clinical trial conducted by Kyowa Kirin to evaluate the effect of G-Lasta on the mobilization of hematopoietic stem cells into peripheral blood in healthy volunteers<sup>\*3</sup>.

G-Lasta is a long-acting G-CSF preparation licensed from Kirin Amgen and has been marketed in Japan since 2014 for decreasing the incidence of febrile neutropenia in cancer patients receiving chemotherapy<sup>\*4</sup>. This approved sustained duration form is expected to contribute to reduce the burden of donor's dosage, hospital visits and hospitalization. Kyowa Kirin also started a phase 2 clinical trial for mobilization of hematopoietic stem cells into peripheral blood for autologous blood stem cell transplantation<sup>\*5</sup> in September 2021 in Japan.

Tomohiro Sudo, Executive Officer, Head of Global Product Strategy Department at Kyowa Kirin commented, "We are very pleased to be able to deliver new value to the area of hematopoietic stem cell transplantation through this approval. We will continue to make steady progress in the phase 2 clinical trial for mobilization of hematopoietic stem cells into peripheral blood for autologous blood stem cell transplantation, and strive to make further contributions to this field."

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 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 4<sup>th</sup> to 6<sup>th</sup> day.

**\*3: About the clinical trial**

The results of the clinical trial was presented at 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT) in March 2021.

**\*4: 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.

**\*5: 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.