

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

Tokyo, Japan, March 12, 2021 --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) product G-Lasta[®] [KRN125, generic name: pegfilgrastim (genetical recombination)] for the mobilization of hematopoietic stem cells into peripheral blood in allogeneic blood stem cell transplantation^{*1} (the "indication") in Japan on March 11.

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 healthy volunteer. The results of the clinical trial will be presented at 47th Annual Meeting the European Group for Blood and Marrow Transplantation (EBMT) to be held online from March 14 to 17 (Central European Time).

G-Lasta is a long-acting G-CSF preparation licensed from Kirin Amgen^{*2} and has been marketed in Japan since 2014 for decreasing the incidence of febrile neutropenia in patients receiving cancer chemotherapy.

"Although allogeneic peripheral blood stem cell transplantation is a transplant method with a relatively low donor burden, the mobilization of hematopoietic stem cells into peripheral blood with G-CSF products requires medication, hospital visits and hospitalization over several days," said Tomohiro Sudo, Executive Officer, Director of Strategy Product Planning Department of Kyowa Kirin. "By adding the indication to G-Lasta, which is a sustained duration form of G-CSF product, we expect to be able to reduce the burden on donors in hematopoietic stem cell transplants."

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

Allogeneic peripheral blood stem cell transplantation is a treatment for malignancies such as leukemia, as well as non-neoplastic blood diseases such as aplastic anemia. In order to harvest hematopoietic stem cells from donors for transplantation into recipients, daily-dose G-CSF products are widely used to mobilize hematopoietic stem cells into peripheral blood. The daily G-CSF formulation is injected subcutaneously once or twice daily, and apheresis (separation and collection of blood cell components) is generally performed using a blood component separator on the fourth to sixth day of administration.

***2: About Kirin-Amgen Inc.**

At the time of its licensing, it was a joint venture between Amgen and Kirin Holdings. In 2017, they have agreed to terminate the joint venture. And it is now a subsidiary of Amgen.