News release

Safety Data from a Clinical Trial of Automated Injection Device of G-Lasta® was Reported

Tokyo, Japan, April 4, 2022 --Kyowa Kirin Co., Ltd. ("Kyowa Kirin", TSE:4151, President and CEO: Masashi Miyamoto) announced that the result from a phase 1 study of automated injection device ("the device") of G-Lasta® [KRN125, generic name: pegfilgrastim (genetical recombination), long-acting Granulocyte Colony-Stimulating Factor (G-CSF)[*1] preparation] was published in Cancer Science.

＝Article information=
"Evaluation of a novel medical device for pegfilgrastim administration"
Tomoyuki Aruga *et al*., Cancer Science, 2022;00:1–8., Article DOI: 10.1111/CAS.15335

This publication is based on the data from a multicenter study in patients with breast cancer undergoing neoadjuvant or adjuvant chemotherapy on outpatient basis to evaluate the safety of pegfilgrastim administration via the device.

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 to decrease the incidence of febrile neutropenia[*2] in patients receiving cancer chemotherapy. In the case that the risk of developing febrile neutropenia is high, patients need to visit a medical institution again for administration of G-Lasta® at least one day after administration of chemotherapy.

This device administers pegfilgrastim about 27 hours after being attached to the patient's abdomen through a timer-controlled dosing function. The study period consisted of four cycles of neoadjuvant or adjuvant chemotherapy with docetaxel plus cyclophosphamide. Pegfilgrastim was administered subcutaneously via the device one time for each cycle of chemotherapy. The study enrolled 35 patients and no serious adverse events or febrile neutropenia occurred. All administrations of the product were successfully completed at all injection procedures and no safety concerns associated with the device function arose.

Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin commented. "We are very pleased to publish the successful results of our phase 1 study assessing safety of the automated injection device. We will continue to push forward with the belief that this

novel device provides additional value in meeting the unmet medical needs for patients who receive cancer chemotherapy."

With applying it to patients on the same day of chemotherapy, an outpatient revisit required for administration of G-Lasta® on the following day can be omitted. With the device, it is expected that burden on both patients and healthcare providers can be reduced. Based on the data from the clinical study, New Drug Application (NDA) was submitted to Ministry of Health, Labour and Welfare (MHLW) in August 2021 in Japan by Kyowa Kirin and has been under review[*3].

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.

***3: About the NDA submission in August 2021**

For more information, please visit the website below.
https://www.kyowakirin.com/media_center/news_releases/2021/pdf/e20210901_01.pdf