News release

Kyowa Kirin Received Approval for Partial Change Approval of Romiplate® for Aplastic Anemia in Japan

Tokyo, Japan, September 25th, 2023 --Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that the company has received approval from the Japanese Ministry of Health, Labour and Welfare for hematopoietic stimulating agent Romiplate® (AMG531, generic name: romiplostim (genetical recombination)) to change the approved indication from “aplastic anemia (AA) [*1] in patients who had an inadequate response to conventional therapy” to “AA” in Japan today.

Romiplate® is composed of recombinant protein acting on the thrombopoietin receptor[*2], which has been licensed from Amgen K-A, Inc. to Kyowa Kirin. It was launched as a drug for idiopathic thrombocytopenic purpura (ITP) in April 2011 and for AA in patients who had an inadequate response to conventional therapy in June 2019 in Japan.

This approval is based on the results of clinical studies of Romiplate® in AA patients untreated with prior immunosuppressive therapy. These studies have met the primary endpoint and the safety profile for Romiplate® was consistent with prior studies, with no new safety signals identified.

"We are very pleased to have obtained this partial change approval, which is a significant step toward the access of Romiplate® for AA patients untreated with prior immunosuppressive therapy,” said Yoshifumi Torii, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin. “It is reported there are cases of inadequate response to AA with existing drugs, and there is a need for new therapeutic options that are safe and highly effective. We strongly hope that Romiplate® will become a new option for implementing the treatment tailored to individual patients."

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 Aplastic Anemia**

Aplastic anemia (AA) is a disease with deficiency of all blood cell types (pancytopenia) and decreases population of stem cells (hypoplasia).

***2: About Thrombopoietin Receptor**

Thrombopoietin receptor is a membrane protein that is essential for hematopoiesis and platelet production.