News release

Kyowa Kirin Announces Application for Partial Change of Romiplate® for Aplastic Anemia in Japan

Tokyo, Japan, November 11, 2022 --Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE:4151, President and CEO: Masashi Miyamoto) announced that the company has filed an application to the Japanese Ministry of Health, Labour and Welfare for partial change of Romiplate® [AMG531, generic name: romiplostim (genetical recombination)] for the treatment of aplastic anemia (AA) [*1] in Japan on November 11th.

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 application 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.

“I am glad that we have submitted the application for partial change of Romiplate® for the treatment of AA in patients without treating prior immunosuppressive agents,” 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 existing drugs in AA, and there is a need for new therapeutic option that is safe and highly effective. We strongly expect that Romiplate® will further meet the unmet medical needs of AA 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 type (pancytopenia) and decreases population of stem cells (hypoplasia). Immunosuppressive drugs and hematopoietic stem cell

transplantation are primary options in the treatment of AA.

***2: About Thrombopoietin Receptor**

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