Kyowa Hakko Kirin Submits Application for Additional Indication for Romiplostim (Recombinant) for Aplastic Anemia in Japan

Tokyo, Japan, July 31, 2018 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and COO: Masashi Miyamoto, "Kyowa Hakko Kirin") announced today that an application seeking approval of an additional indication for romiplostim (code name: AMG531, "the drug") for aplastic anemia (AA) has been filed with Japan's Ministry of Health, Labour and Welfare (MHLW).

The drug is composed of recombinant protein stimulating platelet production via acting on the thrombopoietin receptors. It was launched as a drug for idiopathic thrombocytopenic purpura (ITP) and has contributed to many ITP patients since April 2011.

This application is based on the efficacy and safety of romiplostim for AA demonstrated through the clinical study conducted in Japan and Korea by Kyowa Hakko Kirin. This study has met the primary endpoint and details of the results will be presented at an upcoming scientific conference.

"Submitting this application for romiplostim for AA is a significant step," said Mitsuo Satoh, Ph.D., Executive Officer, Vice President Head of R&D Division of Kyowa Hakko Kirin. "We believe romiplostim will make a difference to AA patients with thrombocytopenia who are refractory to or ineligible for immunosuppressive therapy, by providing safer and more efficacious treatment."

The Kyowa Hakko 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.

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

About Thrombopoietin
Thrombopoietin (TPO) is a main hematopoietic growth factor that stimulates platelet production.

About Idiopathic Thrombocytopenic Purpura
Idiopathic thrombocytopenic purpura is an autoimmune disease in which the person has reduced plateles caused by the production of autoantibody against individual's platelet.

About the Primary Endpoint of Clinical Study
Proportion of subjects achieving a hematological response (any of the platelet response, erythroid response, and neutrophil response) at Week 27.