

Kyowa Hakko Kirin Announces Approval of Darbepoetin Alfa Injection Syringe [KKF] in Japan

Tokyo, Japan, August 16, 2018 – Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and COO: Masashi Miyamoto, "Kyowa Hakko Kirin") announces today that its wholly owned subsidiary Kyowa Kirin Frontier Co., Ltd. (President and CEO: Wataru Murata, "Kyowa Kirin Frontier") received manufacturing and marketing approval (MMA) in Japan on August 15 for "Darbepoetin Alfa Injection Syringe [KKF]."

Darbepoetin Alfa is a Long-Acting Erythropoiesis-Stimulating Agent that was initially approved in Japan in July 2007 and launched in the Japanese market by Kyowa Hakko Kirin under the name of NESP®. As a core product of Kyowa Hakko Kirin, NESP® has been highly recognized for its safety and efficacy for the treatment of anemia in adult chronic kidney disease patients on / not on dialysis and is widely used at a large number of medical institutions. "Darbepoetin Alfa Injection Syringe [KKF]," which has just been approved in Japan, is an "Authorized version*1" of NESP®.

In the future, Kyowa Kirin Frontier will carefully consider the establishment of a stable supply system for the drug as the top priority issue. Kyowa Kirin Frontier plans to proceed with the preparations for sales as soon as the company can secure a stable supply system for the product.

Kyowa Kirin Frontier was established in January 2017 as part of "CSV*2 management based on our unique business structure" within the "Contribution to Health and Well-being of People," which is one of the core strategies set forth by Kyowa Hakko Kirin in the current Mid-term Business Plan. Kyowa Kirin Frontier has worked toward obtaining approval for "Darbepoetin Alfa Injection Syringe [KKF]," and the company plans to jointly sell the product through a collaboration with Kyowa Hakko Kirin in order to utilize Kyowa Hakko Kirin's strength in the Nephrology disease area in Japan that it has developed over the years.

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.

***1 Authorized version:**

Kyowa Hakko Kirin has defined "Authorized version" as an identical drug with the same active pharmaceutical ingredients, excipients and manufacturing method as the branded drug and is manufactured and marketed by a company that has received the right to exploit the branded drug's patent from the company which owns the patent.

***2 Creating Shared Value**

CSV is the abbreviation of "Creating Shared Value." It refers to realizing improved corporate value by bringing about both the "creation of social value" and "creation of economic value" through efforts to address the pressing problems in society.