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Kissei Pharmaceutical Co., Ltd.
JCR Pharmaceuticals Co., Ltd.

JR-131, a Long-Acting Erythropoiesis-Stimulating Agent, Demonstrates Equivalence in Phase III Study

Kissei Pharmaceutical Co., Ltd. (Chairman and CEO: Mutsuo Kanzawa) (“Kissei”) and JCR Pharmaceuticals Co., Ltd. (Chairman and President: Shin Ashida) (“JCR”) jointly announced positive results of the phase III study for JR-131, a proposed biosimilar to darbepoetin alfa, a long-acting erythropoiesis-stimulating agent for the treatment of renal anemia.

In the Phase III study initiated in August 2016, JR-131 demonstrated equivalence in efficacy and safety compared with darbepoetin. Accordingly, in a primary endpoint of efficacy, the equivalence was verified for variations in hemoglobin concentration and the similarity with regard to the safety profile was confirmed.

Kissei and JCR concluded a collaborative research and development agreement for JR-131 in September 2013, and have been advancing the development with the aim to apply for marketing approval in 2018. JR-131 which offers economic efficiency, can become a new treatment option in the renal diseases areas. Both companies are aiming to contribute to healthcare through the development of JR-131, by leveraging JCR’s strong know-how and expertise in biopharmaceutical manufacturing that meets the global quality standards, and Kissei’s outstanding performance in the renal diseases including dialysis areas and sales results of the first biosimilar in Japan, "Epoetin alfa BS Injection [JCR]".