



September 20, 2019

JCR Pharmaceuticals Co., Ltd.

Kissei Pharmaceutical Co., Ltd.

JCR Receives Marketing Approval for Darbepoetin Alfa BS Injection JCR, a Long-Acting Erythropoiesis-Stimulating Agent

JCR Pharmaceuticals Co., Ltd. (TSE: 4552, Chairman and President: Shin Ashida) (“JCR”) and Kissei Pharmaceutical Co., Ltd. (TSE: 4547, Chairman and CEO: Mutsuo Kanzawa) (“Kissei”) announced today that they have received marketing approval in Japan for Darbepoetin Alfa BS Injection JCR, a long-acting erythropoiesis-stimulating agent.

JCR and Kissei Pharmaceutical Co., Ltd. have been conducting the development of a treatment for renal anemia since the two companies entered into a collaborative research and development agreement for JR-131 in September 2013. The Phase III study demonstrated the equivalence in efficacy and safety compared with Darbepoetin alpha (innovator product), along with the similarity in the safety profile.

Darbepoetin Alfa BS Injection JCR will be manufactured by JCR, while its medical information provision and marketing activities will be handled by Kissei. After the NHI price listing, Darbepoetin Alfa BS Injection JCR will be launched by Kissei. Both companies will leverage their experience cultivated from Epoetin Alfa BS Injection JCR, on sale since May 2010, and hope to contribute to enhanced medical treatment by providing Darbepoetin Alfa BS Injection JCR as a new option for treating renal anemia.

〈Product Overview〉

Product name:	Darbepoetin Alfa BS Injection 5μg Syringe JCR Darbepoetin Alfa BS Injection 10μg Syringe JCR Darbepoetin Alfa BS Injection 15μg Syringe JCR Darbepoetin Alfa BS Injection 20μg Syringe JCR Darbepoetin Alfa BS Injection 30μg Syringe JCR Darbepoetin Alfa BS Injection 40μg Syringe JCR Darbepoetin Alfa BS Injection 60μg Syringe JCR Darbepoetin Alfa BS Injection 120μg Syringe JCR Darbepoetin Alfa BS Injection 180μg Syringe JCR
Generic name:	Darbepoetin Alfa (recombinant) [Darbepoetin Alfa Biosimilar 1]
Date of marketing approval:	September 20, 2019
Indications/efficacy:	Renal anemia

〈Renal Anemia and its Treatment〉

Renal anemia is a subtype of anemia caused by insufficient production of erythropoietin (EPO) due to low hemoglobin in the kidneys, but refers only to the cases where no major etiology other than the chronic kidney disease (CKD) is recognized. Chronic renal failure patients undergoing dialysis have various complications involving cardiovascular system, bones, joints etc., amongst which renal anemia is of marked prevalence.

Statistics from the Japanese Society for Dialysis Therapy suggest more than 330,000 chronic dialysis patients in Japan as of the end of 2017. Majority of these patients are reported to be on erythropoiesis-stimulating agents (ESA). Treatment with ESA is also given to the patients with anemia who suffer from renal dysfunction due to conditions such as glomerulonephritis and pyelonephritis but are yet in need of transplant or dialysis.