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Efficacy and safety of CKD-11101 (darbepoetin-alfa proposed biosimilar) compared with Darbepoetin alfa in patient on hemodialysis

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Objectives: Anemia is critical problem which is caused by deficiency of endogenous erythropoietin (EPO) synthesis in patient on dialysis. Darbepoetin-alfa is a useful EPO with long elimination half-life. Herein, we aim to evaluate the efficacy and safety of intravenous CKD-11101 (biosimilar darbepoetin-alfa) compared with darbepoetin-alfa in patients undergoing hemodialysis.

Methods: The study group composed with 24 different institutes was divided by randomized, double-blinded, and prospectively. Follow-up duration was 24 weeks which was consisted with 20 weeks of maintenance and 4 weeks of evaluation period. All patients underwent the stabilization period to achieve target baseline hemoglobin (Hb) as 10-12 g/dL before randomization. After randomization, patients received EPO by weekly or biweekly with adjusted dose following the

permitted rule of darbepoetin alfa. First, we compared the efficacy of CKD-11101 to darbepoetin-alfa. Secondly, we investigated the safety of CKD-11101.

Results: A total of 403 patients were randomized to two different groups during June 2015 and June 2017. Among randomized populations, 78 (19.35%) were dropped-out with major infraction or side effect, 325 (80.65%) patients completed the investigation. The average administered dose of EPO was not different in both groups; 74.90 ± 56.85 mcg and 61.96 ± 43.51 mcg in CKD-11101 and darbepoetin-alfa, respectively. During the study period, the percentage of patients with targeted Hb was 19.44% (28/144), and 20.95% (31/148) with CKD-11101 and darbepoetin-alfa, respectively (p = 0.750). There was no difference in rate of patients need to be changed the dose; 95.83% (138/144) and 93.24% (138/148) with CKD-11101 and darbepoetin-alfa (p = 0.331). There was only one patient who needed to be transfused in each group.

Conclusions: The difference in change of the level of Hb, dose of EPO, and achievement rate to target Hb during study period was comparable between two groups. CKD-11101 has an equivalent therapeutic efficacy compared with the darbepoetin-alfa in patient undergoing hemodialysis.