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Efficacy and safety of CKD-11101 compared with darbepoetin alpha in anemic chronic kidney disease patients not on dialysis

Jong Hoon Lee1, Byung Ha Chung1, Yong-Lim Kim3, Ki Young Na4, Su-Kil Park5, Soo Wan Kim7, Kwon Wook Joo2, Jong Soo Lee6, Chul Woo Yang1
1Department of Internal Medicine-Nephrology, The Catholic University of Korea, Seoul St. Mary’s Hospital, Korea, Republic of
2Department of Internal Medicine-Nephrology, Seoul National University Hospital, Korea, Republic of
3Department of Internal Medicine-Nephrology, Kyungpook National University Hospital, Korea, Republic of
4Department of Internal Medicine-Nephrology, Seoul National University Bundang Hospital, Korea, Republic of
5Department of Internal Medicine-Nephrology, Asan Medical Center, University of Ulsan College of Medicine, Korea, Republic of
6Department of Internal Medicine-Nephrology, Ulsan University Hospital, Korea, Republic of
7Department of Internal Medicine-Nephrology, Chonnam National University Hospital, Korea, Republic of

Objectives: To evaluate the efficacy and safety of CKD-11101 compared with darbepoetin alpha in under target hemoglobin (Hb) level in patients with chronic kidney disease (CKD) stage three or more who are not on dialysis.

Methods: In this multicenter, randomized, double-blind study, 248 patients were treated with CKD-11101 (n=118) and darbepoetin alpha (n=130). During 24 week efficacy evaluation period (EEP), the patients treated subcutaneously every 2 weeks. All patients who completed the EEP were treated with CKD-11101 and evaluated every 4 weeks for safety evaluation period (SEP) from 28 weeks to 52 weeks. The primary efficacy endpoint was change in Hb level from baseline to end of EEP and mean dose of medication to achieve target Hb. Safety endpoints included adverse events (AEs) and adverse drug reactions (ADRs).

Results: The mean Hb level was statistically increased in both group in EEP (both P<0.001). The difference in mean Hb level change between the two treatment groups was 0.01g/dL (95% CI -0.213, 0.242), indicating CKD-11101 was non-inferior to darbepoetin alpha. The difference in mean treatment dose between groups was -1.40mcg (95% CI -6.859, 4.059), and was included in the equivalent range. Incidence of AE, ADRs was not significantly different between the two groups during EEP and SEP (each P>0.05), and frequency of ADR was favorable in both group (1.2% in CKD-11101; 7.7% in darbepoetin alpha to CKD-11101 conversion group)

Conclusions:
CKD-11101 has the equivalent therapeutic effect to the NESP in the treatment of anemia of CKD patients without dialysis. And it can be safely used for long term treatment or when converted from darbepoetin alpha.
Figure 1. Patient disposition

- Screened: n = 322
- Not randomized: n = 74
- Randomized: n = 248
  - Received CKD-11101 (n = 118)
    - Withdrawn during EEP (n = 37)
      - Completed EEP/Started SEP (Maintenance of treatment, n = 81)
        - Withdrawn during EEP (n = 16)
          - Complete SEP (n = 79)
  - Received darbepoetin-alfa (n = 130)
    - Withdrawn during EEP (n = 28)
      - Complete EEP/Started SEP (Conversion to CKD-11101, n = 102)
        - Withdrawn during EEP (n = 21)
          - Complete SEP (n = 83)

Figure 1. Hemoglobin level during efficacy evaluation period