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**Dose Alterations and Hemoglobin (Hb) Control in Chronic Kidney Disease (CKD)
Patients (Pts) on Dialysis**

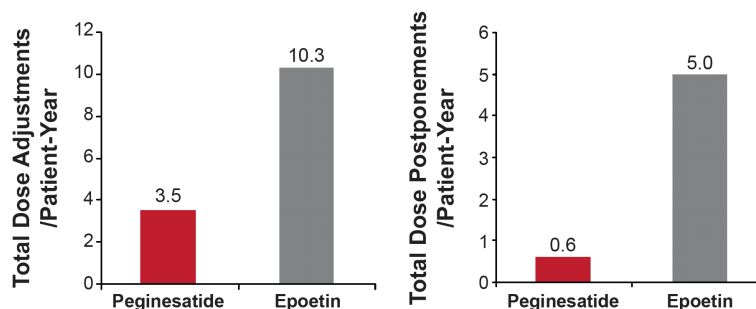
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Purpose: Peginesatide is a once-monthly pegylated, peptide-based erythropoiesis-stimulating agent indicated for treatment of anemia due to CKD in adult pts on dialysis. Peginesatide was noninferior to epoetin in maintaining Hb in hemodialysis pts in two Phase 3 randomized, active-controlled, open-label trials (EMERALD 1, 2; Schiller, ASN 2010). This post hoc analysis assessed the dose alteration frequency and Hb stability for peginesatide vs epoetin.

Methods: Data were pooled from the 2 trials: peginesatide (Q4W; n=1066); epoetin (1-3x/week; n=542). Dose adjustments (>±20% change from prior dose) were not to be made more frequently than Q4W to maintain Hb 10-12 g/dL (per guidelines in effect at time of trial). Hb was measured Q2W, except weekly during period when primary efficacy was evaluated or after dose postponements (defined as >35d after prior peginesatide dose or >4, 6, or 9d after prior epoetin dose TIW, BIW, or QW, respectively). Dose alteration frequency was calculated per pt-year of exposure. Hb excursions were defined by 2 consecutive values >13 g/dL or <10 g/dL.

Results: Dose alterations (adjustments/postponements) for the entire study period are presented (Figure). For the duration of the study, the two groups had comparable Hb levels and Hb excursions >13 g/dL (22% vs 20% pts; median 22 vs 20 days/excursion) and <10 g/dL (54% vs 51% pts, 38 vs 39 days/excursion). Proportion of pts with rapid Hb rise (>2 g/dL per 4 weeks) and rates of Hb decline following dose postponements (g/dL/week) were similar between groups.

Conclusion: Per pt-year, peginesatide pts had fewer dose alterations than epoetin. Hb stability was similar between groups, based on Hb stability data, including Hb excursions, proportion of pts with rapid Hb rise, and rates of Hb decline following dose postponements. The results suggest that peginesatide may achieve similar Hb outcomes and has fewer dose alterations than epoetin.



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