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Time to Initial Peginesatide Dose Stability in Hemodialysis Patients

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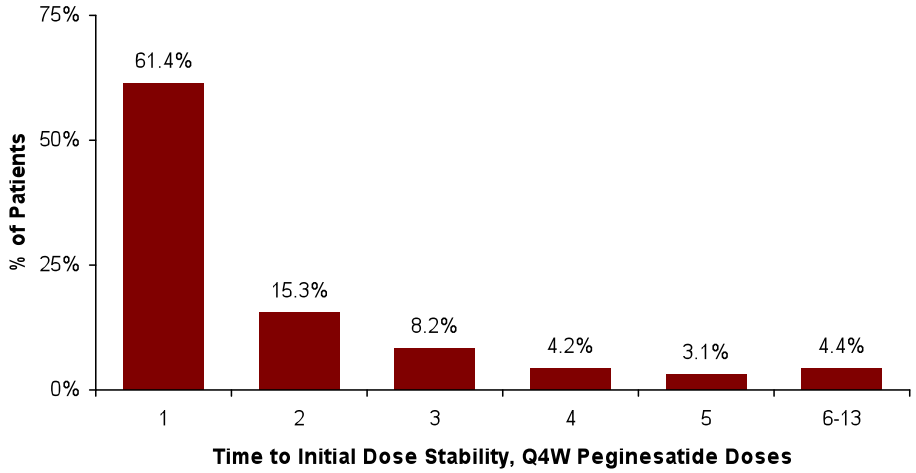
Purpose: Peginesatide is a pegylated, peptide-based erythropoiesis-stimulating agent (ESA) indicated for treatment of anemia due to chronic kidney disease in adult patients on dialysis. In two Phase 3 randomized, active-controlled, open-label trials (EMERALD 1, 2) for hemodialysis (HD) patients, peginesatide demonstrated noninferiority to epoetin in maintaining hemoglobin (Hb; Schiller et al. ASN 2010). This post hoc analysis evaluated the number of peginesatide doses given Q4W required to achieve initial dose stability following conversion from stable epoetin to peginesatide.

Methods: Data were pooled from the two trials assessing safety and efficacy of peginesatide (Q4W; n=1066) vs epoetin (1-3x weekly; n=542) in HD patients. Dose adjustments were to be made no more frequently than Q4W (unless required for safety purposes) to maintain Hb 10-12 g/dL (per guidelines in effect at time of trial). Hb was measured Q2W (or QW during the period when primary efficacy was evaluated or after dose postponements). Initial dose stability was established if (1) the subsequent dose was within 20% of prior dose (4 weeks ±7 days between doses), and (2) at least 1 Hb was within target between doses. For establishing stability, patients had to receive ≥2 doses (n=1034) to be included in the analysis.

Results: Initial dose stability was reached in 61.4% of patients after the first dose, 76.7% by the second dose, 85% by the third dose (Figure). Only 4.4% of patients required 6 or more doses to achieve initial dose stability.

Conclusion: This analysis demonstrated that conversion from stable epoetin to peginesatide in HD patients was successful, with the majority of patients reaching initial dose stability within 1 to 2 doses of peginesatide.

Figure. Distribution of Doses to Initial Dose Stability



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