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Peginesatide and Epoetin Doses in Patients on Dialysis

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Purpose: Peginesatide is a once-monthly, synthetic, investigational, peptide-based erythropoiesis-stimulating agent (ESA) that stimulates the erythropoietin receptor. Two phase 3 trials were conducted to assess the safety and efficacy of peginesatide compared to epoetin alfa/beta (EMERALD 1 and 2). This analysis evaluated the relative dose of peginesatide compared with epoetin in patients on dialysis.

Methods: 1608 patients on dialysis who were receiving stable epoetin doses were enrolled in two randomized, open-label trials comparing peginesatide once monthly to epoetin 1-3 times weekly. The relationship between baseline epoetin dose and mean ESA dose during the evaluation period (wks 29-36) was evaluated. The baseline epoetin dose during the week prior to randomization was determined for each patient and divided into "low" and "high" baseline epoetin dose groups that represent the bottom and top 25% of patients. The dose ratio (baseline epoetin dose to mean evaluation period peginesatide or evaluation period epoetin dose) was calculated for each patient.

Results: The relative dose of peginesatide for patients receiving high epoetin doses at baseline was less than half that for patients receiving low epoetin doses at baseline (**Table**). Mean hemoglobin levels were similar at baseline and during the evaluation period for both treatment groups.

Table

	Mean Baseline Epoetin Dose[1] (U/week)	Mean Peginesatide Dose[1] (mg/mo)	Median Dose Ratio[2] Baseline Epoetin:Peginesatide
Low	2900	3	1040:1
High	32000	15	2150:1

[1]Mean dose given to top ("high"; ≥16,400 U/wk) or bottom ("low"; ≤4800 U/wk) 25% of patients based on baseline epoetin doses across all patients in study; [2]Calculated as median of ratios for each patient within low or high dose groups.

Conclusions: These findings suggest that patients who require more epoetin at baseline tend to require relatively less peginesatide.

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