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Intravenous and Subcutaneous Administration of Peginesatide and Epoetin in US and Non-US 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 compared intravenous (IV) versus subcutaneous (SC) doses in US and non-US patients.

Methods: 1608 patients on dialysis were enrolled in 2 randomized, open-label trials comparing peginesatide once monthly to epoetin 1-3 times weekly. The drugs were administered using the same route that was used during screening. Mean hemoglobin and dose during the evaluation period (weeks 29-36) were calculated for each patient and summarized by treatment group and route.

Results: Median epoetin doses tended to be lower for the SC than IV administration route, whereas this was not observed for peginesatide (**Table**). ESA doses were higher in US than non-US patients for both routes. Mean hemoglobin levels were similar at baseline and during the evaluation period for all patients regardless of administration route. For US patients, a mean total of 2159 mg versus 2413 mg of IV iron were administered to the peginesatide and epoetin groups during weeks 0-52, respectively. For non-US patients, these were 2617 mg versus 2604 mg, respectively.

Evaluation Period	Peginesatide (mg)		Epoetin (U/wk)	
	IV	SC	IV	SC
US Patients				
Median dose*	5.6 [n=683]	6.8 [n=33]	9800 [n=374]	7200 [n=15]
Non-US Patients				
Median dose*	3.5 [n=138]	3.9 [n=62]	5000 [n=61]	4100 [n=27]

*Median of the mean dose patients received during the evaluation period.

Conclusions: Peginesatide doses were not lower with SC compared with IV administration in these patients. Both SC and IV routes of administration can be used for both drugs. Consistent with the findings from previous studies, ESA doses were higher in US than non-US patients despite similar hemoglobin levels.

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