EVALUATION OF THE SAFETY OF FERUMOXYTOL IV IRON THERAPY IN PERITONEAL DIALYSIS PATIENTS

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Ferumoxytol, an iron oxide nanoparticle coated with polyglucose sorbitol carboxymethylether, is being developed as a novel IV iron replacement therapy. Ferumoxytol has been evaluated in Phase II and Phase III trials in subjects with all stages of chronic kidney disease (CKD). Subjects with CKD stage 5D on peritoneal dialysis (PD) were included in a phase III double-blind, crossover study evaluating safety, in which subjects were randomized to either a single dose of ferumoxytol (1x510mg) or an equal volume of saline (17 mL), and 7 days later, to receive the alternate agent. (ClinicalTrials.gov NCT00255450)

Safety was assessed by close monitoring of vital signs immediately after study drug administration, routine lab tests and observation for adverse events (AEs). Safety was examined in subjects with CKD stage 5D on PD, and results were compared with the CKD study population overall.

A total of 43 subjects were observed after receiving ferumoxytol (1x510mg) and 39 after receiving placebo. Overall, subjects reported fewer adverse events following ferumoxytol than following placebo. There were no SAEs reported.

Summary of Treatment Emergent Adverse Events

	Ferumoxytol N=43	**Placebo N=39**
All AEs	7 (16.3%)	8 (20.5%)
Related AEs	2 (4.7%)	3 (7.7%)
All SAEs	0 (0.0%)	0 (0.0%)
Related SAEs	0 (0.0%)	0 (0.0%)

The rate of all and related AEs was comparable to the rate observed in the overall CKD population given 1x510 mg ferumoxytol (18.9% all AEs and 4.7% related AEs, respectively). Ferumoxytol appears to be well tolerated in subjects with CKD stage 5D on PD.