Evaluation of Ferumoxytol Safety and Efficacy in all Stages of Chronic Kidney Disease (CKD)

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Ferumoxytol, an iron oxide nanoparticle coated with polyglucose sorbitol carboxymethylether, is being developed as a novel IV iron replacement therapy. Data were pooled from three Phase III, randomized, controlled, open-label trials in subjects with all stages of CKD Two studies enrolled subjects with CKD stages 1-5 and one study enrolled subjects with CKD stage 5D in HD. (ClinicalTrials.gov NCT00255437, NCT00233597 and NCT00255424).

Subjects were randomized to ferumoxytol (total N=596) or oral iron (total N=278). The primary efficacy endpoint was the mean change from baseline in hemoglobin (Hgb) 5 weeks after the first dose of study drug. Safety was assessed throughout the trial. Subjects were stratified by CKD stage for this post-hoc analysis.

The proportion of subjects on ESA was similar in the two treatment groups. Baseline Hgb ranged from 9.40 to 10.76 g/dL (highest in CKD stage 5D), but was similar across the two treatment groups. Change from baseline in Hgb at 5 weeks is shown in the table below.

Hemoglobin (g/dL) Response at Week 5 (values are mean±SD)

	Ferumoxytol (N=596)		**Oral Iron (N=278)**	
CKD Stage	N	Change from baseline	N	Change from baseline
Stage 1 and 2	7	1.74±1.59	3	1.80±1.72
Stage 3	162	1.17±1.16	58	0.45±0.90
Stage 4	204	1.02±1.23	75	0.26±1.08
Stage 5	55	0.82±1.59	12	0.32±1.04
Stage 5D	168	0.96±1.11	130	0.48±1.06

Across all stages of CKD, a larger proportion of subjects in the oral iron group reported adverse events than in the ferumoxytol group.

Ferumoxytol was well tolerated and consistently increased hemoglobin to a clinically meaningful extent in subjects with all stages of CKD.