Introduction

- Dietary phosphate intake and serum phosphate levels are each independently associated with harm in patients with CKD.
- Previous randomized clinical trials have shown limited ability of currently commercially available phosphate binders (PB) to reduce serum phosphate in this patient group.
- Iron Deficiency Anemia (IDA) is common in patients with CKD and is associated with increased mortality.
- IDA often untreated due to adverse effects or logistical issues related to use of ESA and IV iron.
- To determine the safety and efficacy of Zerenex™ (ferric citrate) in the treatment of iron deficiency anemia in patients with non-dialysis dependent CKD and elevated serum phosphate.

Methods

- This trial was sponsored by Keryx Biopharmaceuticals, Inc.
- Primary Endpoint: Between group change in TSAT and serum P from pre to 12 week treatment period
- Secondary Endpoints: Between group change in hemoglobin, Ferritin, FGF23 and urinary P

Design

- Multi-center, double-blind, placebo controlled RCT
- 2 week washout for subjects on PB binders
- 12 week treatment period
- FCCC administered at starting dose 1 tablet (210 mg elemental iron) per meal (3 per day), titrated to achieve serum P < 3.5 mg/dL, to maximum of 12 tablets per day

Key Inclusion Criteria:

- Adult patients with CKD and elevated serum P
- NDD-CKD and reduction of serum P in patients with IDA and serum P > 6.0 mg/dl

Key Exclusion Criteria:

- Use of ESA within 4 weeks of screening
- Use of IV iron within 8 weeks of screening
- Cause of anemia other than CKD or IDA
- Active GI bleeding or inflammatory bowel disease

Results

Table 1: Baseline characteristics of subjects in modified ITT analysis

Table 2: Adverse Events

Figure 1: Patient Disposition

Figure 2: Primary and Secondary Iron Related Endpoints

Figure 3: Primary and Secondary Phosphate Related Endpoints

Conclusions

- 12 week treatment with Ferric Citrate Coordination Complex in patients with IDA and serum P > 4.0 mg/dl, resulted in:
  - Repletion of iron stores as indicated by statistically significant increases in TSAT and ferritin
  - Clinically and statistically significant increases in hemoglobin without the use of ESA or IV iron
  - Reduction in mean serum P > 4.0 mg/dl.
  - 40% reduction in median FGF23
  - A safety profile comparable with placebo control
- These results are supportive of further clinical development of FCCC for the treatment of IDA and reduction of serum P in patients with NDD-CKD.