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Oxylanthanum Carbonate for Hyperphosphatemia in ESKD: Tolerability Trial in Progress

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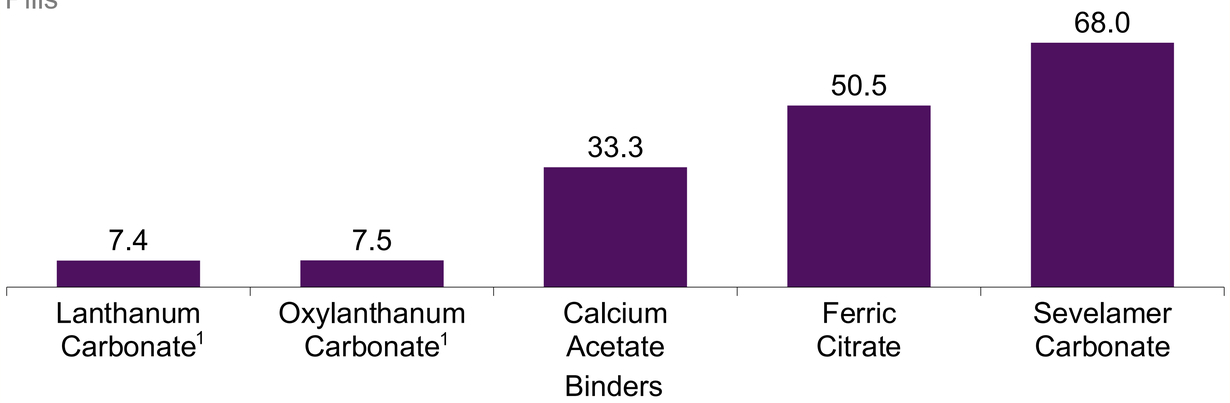
BACKGROUND

- Despite current therapies, more than 43% of patients undergoing dialysis in the USA have hyperphosphatemia, defined as serum phosphate values >5.5 mg/dL and is commonly associated with an increased risk of death[1]
- Most currently available phosphate binders are known to cause gastrointestinal (GI) adverse events (AEs) that can negatively impact the patient experience[2]
- Common GI AEs with phosphate binders include abdominal pain, nausea, and bloating
- Phosphate binders are usually formulated as large tablets, and some must be chewed before ingestion[2]
- Each day a high number of phosphate binder pills are typically needed to achieve serum phosphate goals
- Oxylanthanum carbonate (OLC) is a new lanthanum-based nanotechnology product in development with a high in vitro binding capacity as compared to other phosphate binders
- OLC is formulated as a small pill that is swallowed whole instead of being chewed before swallowing as is the case for lanthanum carbonate **(Figure 1)**
- The safety of OLC has been studied in >100 healthy subjects
- The most common treatment-related AE (>5%) in an OLC bioequivalence (BE) study was nausea

Figure 1. Number of Pills to Bind 1g of Phosphate by Binder – Estimated with Dose



1 1,000 mg La

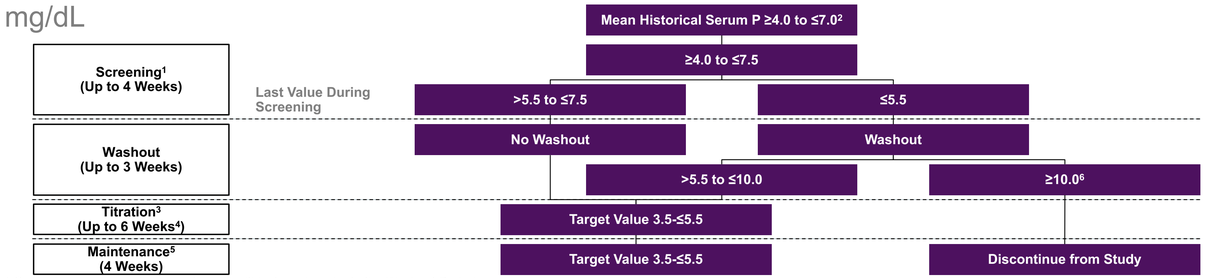
OBJECTIVE

This study aims to evaluate the tolerability of clinically effective (serum phosphate ≤5.5 mg/dL) doses of OLC in patients on hemodialysis

METHODS

- This open-label, single-arm, multicenter, multidose study will enroll up to 90 patients on hemodialysis who require phosphate binder therapy and have mean historical serum phosphate levels between ≥4.0 and ≤7.0 mg/dL for ≥8 weeks
- The primary endpoint of the study is tolerability as assessed by the incidence of discontinuations due to treatment-related AEs
- In addition to AEs, the pharmacokinetics of OLC will be evaluated
- Participants will undergo up to 3 weeks of phosphate binder washout until their serum phosphate levels reach >5.5 and ≤10.0 mg/dL **(Figure 2)**
- During the 6-week Titration Period, all patients will receive 1500 mg/day OLC (500 mg TID with meals/snacks) for the initial 2 weeks, with subsequent titration every 2 weeks until achieving a target serum phosphate level (≤5.5 mg/dL) or to a maximum OLC dose of 3000 mg/day
- After titration, patients will enter a 4-week Maintenance Period at the effective OLC dose

Figure 2. Study Design – Titration by Serum Phosphorous



1 Screening assessments are performed within 4 weeks prior to the Washout Period
2 Eligible patients have mean historical serum phosphorous ≥4.0 to ≤7.5 while on their current phosphate binder for at least 8 weeks prior to Screening
3 Starting dose 500 mg TID to maximum dose 1,000 mg TID or 1,500 mg BID
4 Doses are titrated every 2 weeks until patients reach the target serum phosphate range (≤5.5 mg/dL), up to 6 weeks
5 Safety analysis and renal panel, including phosphate concentrations, will be evaluated every week; Patient will reinitiate their prior standard therapy on the day after the last dose of OLC
6 2 consecutive values

RESULTS

We intend to present results elucidating tolerability of clinically effective doses of OLC in patients on dialysis

CONCLUSIONS

The tolerability of OLC at doses effective in achieving a serum phosphate ≤5.5 mg/dL in patients on hemodialysis will be evaluated in this study

References:
1. USRDS. USRDS Annual Data Report. 2020.
2. Wang S. et al., J Ren Nutr. 2014. Mar.

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