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A Phase 2 Clinical Trial of Oxylanthanum Carbonate in Patients Receiving Maintenance Hemodialysis with Hyperphosphatemia

--Manuscript Draft--

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Abstract:	Background. In patients with kidney failure receiving maintenance dialysis, hyperphosphatemia is managed by dietary phosphate restriction and the provision of phosphate binders. Oxylanthanum carbonate (OLC) is a phosphate binder in development with high potency and formulated in a small pill swallowed whole. Methods. We conducted a Phase 2, open-label, single-arm, multicenter trial in adult patients receiving maintenance hemodialysis with hyperphosphatemia. The primary objective was to evaluate the tolerability of OLC at clinically effective doses with a goal serum phosphate concentration (sP) ≤5.5 mg/dL. The trial included washout, titration, and maintenance periods. Eligible patients had sP ≥4.0 and ≤7.5 mg/dL for at least eight weeks prior to screening while receiving thrice weekly hemodialysis and a stable phosphate binder regimen. Patients started titration when sP was >5.5 mg/dL and entered maintenance once sP was ≤5.5 mg/dL. The starting dose of OLC during

	titration was 1500 mg/day (500 mg thrice daily). We assessed tolerability based on the incidence of discontinuations due to treatment-related adverse events (TRAEs). Results. Eighty-six patients were treated with OLC during the study. At screening, sP was ≤5.5 mg/dL in 51 (59%) patients. Seventy-eight (91%) patients entered maintenance, and 71 (91%) patients achieved sP ≤5.5 mg/dL on a median OLC dose of 500 mg TID. The most common TRAEs were gastrointestinal and included diarrhea (9%) and vomiting (6%); all other TRAEs were reported in <5% of patients. Three (4%) patients discontinued drug due to TRAEs. Minimal to no systemic absorption of lanthanum was observed following administration of OLC 1000 mg thrice daily. Conclusion. In this open-label Phase 2 trial, OLC was well tolerated and enabled sP control in >90% of patients with a low pill burden (two-thirds of patients receiving three or fewer tablets/day). Clinical Trial registry name and registration number: NCT06218290
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Declaration of Helsinki: For all clinical experimentation described in the manuscript, I have stated in the Methods section adherence to the Declaration of Helsinki. A statement that informed consent was obtained also appears in the manuscript, and I have specified the name of the institutional review board or equivalent that approved the study.	Yes
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Declaration of Helsinki For all clinical experimentation described in the manuscript, I adhered to the Declaration of Helsinki and indicated my response below accordingly.	This study includes clinical experimentation and complies with the Declaration of Helsinki.
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Key Points: Please state the 2-3 key points of the article. The responses included here will be included with your final published paper. The key points should be complete statements and not duplications of your keywords or index terms. At least two key points are required.	Key Point 1; Key Point 2; Key Point 3
Key point #1:	Oxylanthanum carbonate (OLC) was well tolerated with fewer than 10% of patients

as follow-up to "Key Points: Please state the 2-3 key points of the article. The responses included here will be included with your final published paper. The key points should be complete statements and not duplications of your keywords or index terms. At least two key points are required."	stopping treatment due to side effects.
Key point #2: as follow-up to "Key Points: Please state the 2-3 key points of the article. The responses included here will be included with your final published paper. The key points should be complete statements and not duplications of your keywords or index terms. At least two key points are required."	More than 90% of patients with hyperphosphatemia taking OLC achieved effective phosphate control.
Key point #3: as follow-up to "Key Points: Please state the 2-3 key points of the article. The responses included here will be included with your final published paper. The key points should be complete statements and not duplications of your keywords or index terms. At least two key points are required."	Two-thirds of patients required three or fewer OLC tablets per day to control serum phosphate.

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A Phase 2 Clinical Trial of Oxylanthanum Carbonate in Patients Receiving Maintenance Hemodialysis with Hyperphosphatemia

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ABSTRACT

Background. In patients with kidney failure receiving maintenance dialysis, hyperphosphatemia is managed by dietary phosphate restriction and the provision of phosphate binders. Oxylanthanum carbonate (OLC) is a phosphate binder in development with high potency and formulated in a small pill swallowed whole.

Methods. We conducted a Phase 2, open-label, single-arm, multicenter trial in adult patients receiving maintenance hemodialysis with hyperphosphatemia. The primary objective was to evaluate the tolerability of OLC at clinically effective doses with a goal serum phosphate concentration (sP) ≤5.5 mg/dL. The trial included washout, titration, and maintenance periods. Eligible patients had sP ≥4.0 and ≤7.5 mg/dL for at least eight weeks prior to screening while receiving thrice weekly hemodialysis and a stable phosphate binder regimen. Patients started titration when sP was >5.5 mg/dL and entered maintenance once sP was ≤5.5 mg/dL. The starting dose of OLC during titration was 1500 mg/day (500 mg thrice daily). We assessed tolerability based on the incidence of discontinuations due to treatment-related adverse events (TRAEs).

Results. Eighty-six patients were treated with OLC during the study. At screening, sP was ≤5.5 mg/dL in 51 (59%) patients. Seventy-eight (91%) patients entered maintenance, and 71 (91%) patients achieved sP ≤5.5 mg/dL on a median OLC dose of 500 mg TID. The most common TRAEs were gastrointestinal and included diarrhea (9%) and vomiting (6%); all other TRAEs were reported in <5% of patients. Three (4%) patients discontinued drug due to TRAEs. Minimal to no systemic absorption of lanthanum was observed following administration of OLC 1000 mg thrice daily.

Conclusion. In this open-label Phase 2 trial, OLC was well tolerated and enabled sP control in >90% of patients with a low pill burden (two-thirds of patients receiving three or fewer tablets/day).

Supplemental Digital Content: http://links.lww.com/CJN/C339

INTRODUCTION

More than half of patients who receive hemodialysis experience hyperphosphatemia, defined as serum phosphate concentration (sP) >4.5 mg/dL.[1] Hyperphosphatemia is associated with vascular, valvular, and myocardial calcification and increased risks of all-cause and cardiovascular mortality.[2-9] Serum phosphate concentrations within or near the population reference range are associated with enhanced survival[8] and delayed progression of coronary artery calcification and bone disease.[2,6] Although the Kidney Disease: Improving Global Outcomes (KDIGO) 2017 guidelines recommend lowering phosphate levels "toward the normal range" of 2.5–4.5 mg/dL in patients with chronic kidney disease (CKD) stages G3a–G5D, achieving this target is often impractical in hemodialysis populations due to severe phosphate retention, dietary limitations, and the pill burden associated with binder therapy. Most clinicians recognize that a target of ≤5.5 mg/dL offers a realistic balance between efficacy, safety, and adherence, and it is incorporated as a goal into most dialysis clinic protocols.

An ideal phosphate binder would combine high phosphate-binding capacity with minimal systemic absorption, excellent safety and tolerability, low pill burden, and improved convenience (small tablet size, swallowed whole rather than chewed). Oxylanthanum carbonate (OLC) is a lanthanum-based phosphate binder in development for the treatment of hyperphosphatemia in patients with end-stage kidney disease (ESKD) that utilizes proprietary nanoparticle technology and has a lower molecular weight than lanthanum carbonate. The nanoparticle technology results in OLC tablets having higher surface area with greater porosity, allowing for improved dissolution in the gastrointestinal tract, rendering more lanthanum available for phosphate binding throughout the gastrointestinal tract compared with lanthanum carbonate. Moreover, 500 mg OLC is formulated in a round tablet 12 mm in diameter with a total volume of 0.35 cm^3

swallowed whole in contrast to 500 mg chewable lanthanum carbonate tablets, 20 mm in diameter with a total volume of 1.33 cm^3. [10]

In this study, we aimed to assess the tolerability of OLC at clinically effective doses, defined as those that achieve and maintain serum phosphate concentrations ≤5.5 mg/dL.

METHODS

Patients

Men and women ≥18 years at screening were eligible for participation if they were undergoing thrice weekly maintenance hemodialysis for at least 12 weeks, had mean sP 4.0 – 7.0 mg/dL inclusive while on phosphate binders over the prior eight weeks, sP 4.0 –7.5 mg/dL inclusive during screening, no change to their prescription for calcimimetic agents or vitamin D receptor activators over the prior four weeks, and single-pool K_t/V_{urea} ≥1.2 at the most recent assessment before screening. Key exclusion criteria included treatment with a lanthanum-based phosphate binder over the prior eight weeks, serum intact parathyroid hormone (PTH) concentration >1500 pg/mL over the prior three months, or history of inflammatory bowel disease, irritable bowel syndrome with diarrhea, malabsorption syndrome, or a recent procedure affecting gastrointestinal function.

Study Design

We conducted the trial at seven centers in the United States (US) between December 2023 and May 2024. Oxylanthanum carbonate was supplied as immediate-release tablets containing 665.60 mg OLC equivalent to 500 mg elemental lanthanum as the active ingredient (hereafter referred to as 500 mg OLC tablets). We selected OLC doses on the basis of results from a first-in-human study of OLC[11] along with the development program of, and clinical experience with, lanthanum carbonate. All tablets were swallowed whole with or immediately

after meals/snacks up to three times a day. Because the study's aim was to assess OLC tolerability at effective doses, dietary counseling was not provided beyond usual care, and no controlled diet was mandated.

This trial was conducted in accordance with the Declaration of Helsinki. All patients provided written informed consent before trial entry. All participating sites obtained independent ethics committee/institutional review board approval. The trial was registered with clinicaltrials.gov (NCT06218290).

Procedures

Patients were assessed weekly for up to a total of 17 weeks (Supplemental Figure 1). After an up to four-week screening period, the trial included three phases: a washout period (1–3 weeks), an open-label titration period (up to six weeks), and a four-week open-label maintenance period.

Washout Period (1–3 weeks): Patients stopped taking their previously prescribed phosphate binders. Patients whose sP did not rise to >5.5 mg/dL within this period were discontinued from the trial. Patients with screening sP >5.5 to ≤7.0 mg/dL entered titration directly without washout (N=35).

Titration Period (up to six weeks): Once sP >5.5 mg/dL was reached, patients initiated the titration period (N=86). For the first two weeks of the titration period, all patients were treated with 1500 mg/day OLC (500 mg thrice daily with meals/snacks). OLC doses were adjusted every two weeks up to a maximum of 3000 mg/day until patients reached the target sP ≤5.5 mg/dL. Investigators could titrate OLC doses more often if it was deemed necessary for patient safety. Patients who achieved sP ≤5.5 mg/dL earlier than six weeks advanced to the maintenance period. Patients whose sP remained >5.5 mg/dL at the end of six weeks of titration continued

titration during the maintenance period if they had not reached the maximum dose or continued at the maximal dose based on the Investigator's judgement. A subset of 14 patients was treated with 3000 mg/day for the first two days for pharmacokinetic assessment. After six doses, these patients resumed titration with 1500 mg/day.

Maintenance Period (4 weeks): The dose of OLC that lowered sP to ≤5.5 mg/dL was identified for each patient during the titration period and was continued during the maintenance period ('clinically effective dose'). Dose modifications were allowed during the maintenance period based on sP and safety. After two weeks, patients with sP >5.5 to 6.0 mg/dL, >6.0 to 6.5 mg/dL, or >6.5 mg/dL, had their OLC dose increased by 500 to 1500 mg/day up to a maximum dose of 3000 mg/day (either 1000 mg thrice daily or 1500 mg twice daily). If patients had two consecutive sP ≥10 mg/dL, they were to be withdrawn from the study and resume usual care. The OLC dose was reduced by 500 mg/day for patients with sP <4.0 mg/dL, and OLC was withheld for patients with sP <3.5 mg/dL until sP rose above 4.0 mg/dL. Treatment was then resumed at the lowest of either 1000 mg/day or 500 mg/day below the last dose taken before pausing OLC treatment.

Study Objectives and Assessments

We assessed tolerability weekly based on the incidence of discontinuations due to treatment-related adverse events (TRAEs). Serum phosphate was assessed weekly. At the end of the study, patients reinitiated their prior phosphate binder therapy.

The primary objective was to evaluate the tolerability of clinically effective doses of OLC. The primary endpoint for tolerability was the incidence of discontinuations due to TRAEs. We defined 'baseline' as the last laboratory measurement prior to the first dose of study drug.

Safety Outcomes and Assessments

We assessed safety based on reported/elicited treatment-emergent adverse events (TEAEs), vital signs, physical examinations, clinical laboratory assessments, including kidney function panel, sP, and 12-lead electrocardiograms. Serial iPTH values were not collected.

The assessment of TEAEs included serious adverse events (SAEs), TEAEs leading to study drug discontinuation, and TRAEs, based on the investigators' assessment. We employed the Medical Dictionary for Regulatory Activities (MedDRA) version 26.0 for assigning System Organ Class and Preferred Term. Prior to discontinuing a patient for a TEAE, we attempted a reduction in the dose of OLC for symptom management.

Pharmacokinetics

A secondary objective was to assess OLC pharmacokinetics. We drew pharmacokinetic (PK) blood samples on all subjects for sparse PK sampling on the first day of each period beginning with the washout period and at the end-of-study visit.

A subset of 14 patients had additional PK blood samples drawn for intensive PK analysis on day 1 of titration. These patients received OLC 1000 mg thrice daily for the first two days. We drew PK samples pre-dose, and at 1, 2, 4, 6, 12, 24, and 48 hours after the first dose of OLC. These 14 patients were required to take all three doses of study drug each day.

We measured serum lanthanum concentrations using a validated inductively coupled plasma tandem mass spectrometry (ICP-MS/MS) assay with a lower limit of quantitation of 0.5 ng/mL. We imputed values below the lower limit of quantification (LLOQ) as 0. We performed noncompartmental pharmacokinetic analysis using Phoenix WinNonlin software (version 8.3) (Certara) to estimate area under the concentration versus time curve (AUC), maximum observed

concentration (C_{max}), time of maximum observed sample concentration (T_{max}), and time of final quantifiable concentration (T_{last}).

Patient Satisfaction

As an exploratory objective, we evaluated patient satisfaction with their previously prescribed phosphate binder therapy compared to OLC. Patients completed sponsor-developed questionnaires to assess satisfaction, perceived pill burden, and adherence to treatment. We administered patient satisfaction surveys at the screening visit (reflecting their previously prescribed phosphate binder therapy) and at the end-of-study visit (reflecting their use of OLC) (Supplemental Materials).

Statistical Analysis

This trial was not powered to test a specific hypothesis, and the sample size was not based on statistical assumptions. Approximately 70% of patients were expected to achieve target sP ≤5.5 mg/dL within the six-week titration period with OLC. We planned to enroll approximately 90 patients to have at least 60 evaluable patients who entered the maintenance period. The evaluable population included all patients who achieved target sP and received at least one dose of OLC in the maintenance period. The safety population, which consisted of all patients who received at least one dose of OLC, was used for calculating all safety and tolerability results. We conducted all statistical analyses using SAS® version 9.3 or later (SAS Institute, Cary, NC, USA).

RESULTS

Patient Disposition and Baseline Characteristics

As shown in **Figure 1**, 128 patients were screened, and 106 patients were enrolled. Of these, 71 patients entered the washout period, and 35 patients had sP >5.5 to ≤7.5 mg/dL and immediately entered the titration period. Fifty-one (72%) of 71 patients who entered the washout period continued to the titration period once their sP exceeded 5.5 mg/dL; 20 (28%) patients failed to reach a sP >5.5 mg/dL during washout and were discontinued from the study. The safety population comprised 86 patients who entered the titration period and the evaluable population comprised 71 patients who achieved sP ≤5.5 mg/dL by the end of the titration period and received at least one dose of OLC during the maintenance period. The mean (standard deviation [SD]) age of patients in the safety population was 63 (±11) years and ranged from 29 to 82; the study sample was 45% women and 34% of non-White race (**Table 1**). Seven patients did not achieve phosphate control during titration but continued treatment during the maintenance period. A total of 14 (16%) patients discontinued study participation; eight patients during the titration period and six patients during the maintenance period. Five (6%) patients were discontinued due to TEAEs, six (7%) patients withdrew consent (no reason specified), and three (4%) patients were discontinued from the study by the investigators: one patient each due to poor adherence, kidney transplantation, and hospitalization. Four of six patients who withdrew consent had a TEAE temporally associated with their dates of withdrawal, but these were all mild in severity.

At study entry, 45 (52%) patients were taking sevelamer, 17 (20%) calcium acetate, and 25 (29%) iron-based binders; two patients were taking a combination of two phosphate binders and one patient was taking tenapanor as monotherapy. Other baseline characteristics are shown in **Table 1**.

The median duration of treatment with OLC was 49 days and ranged from 1 to 71 days in the safety population and 28 to 71 days in the evaluable population. The median dose of OLC during the maintenance period was 1500 mg/day. Final doses for patients in both populations during the titration period and maintenance period ranged from 500 to 3000 mg/day (**Figure 2A**).

Study Assessments

Serum Phosphate

The clinical efficacy of OLC to control sP was not the primary objective; rather, we evaluated the tolerability of OLC at a clinically effective dose (i.e., dose that achieved sP ≤5.5 mg/dL). As shown in **Figure 2b**, at the screening visit, sP was adequately controlled (≤5.5 mg/dL) for 51 (59%) patients, and the mean sP for all patients was 5.5 mg/dL (range: 4.0–7.5 mg/dL). Thirty-five patients had baseline sP >5.5 to ≤7.5 mg/dL (mean sP 6.2 (±0.5) mg/dL) and immediately started the titration period without washout. The mean screening sP of the remaining 51 patients in the Safety Population was 4.9 (±0.4) mg/dL and rose to 6.4 (±0.8) mg/dL during the washout period .

Of the 78 patients who completed the titration period and started the maintenance period, 71 (91%) patients achieved sP control (≤5.5 mg/dL; mean sP 4.7 (±0.5) mg/dL) during titration with a median dose of 1500 mg/day. Forty-nine (69%) patients achieved serum P ≤5.5 mg/dL with ≤1500 mg/day (≤3 tablets/day) (**Figure 2A**). At the end of study, 44 (51%) patients reported

taking ≤3 OLC tablets/day compared to 23 (27%) patients taking ≤3 pretrial phosphate binder tablets/day (**Figure 2C**).

Safety Assessments

Treatment-Emergent AEs: A summary of TEAEs by treatment population is presented in **Table 2a**. In the safety population, 30 (35%) patients experienced TEAEs. Most TEAEs (19%) were mild in severity, 9% were of moderate severity, and 7% were severe, with each severe TEAE reported in one patient each. Most TEAEs were in the gastrointestinal disorders category (20%) and the only TEAEs reported in more than 5% of patients were diarrhea (12%) and vomiting (6%) (**Table 2B**). Most reports of diarrhea and all reports of vomiting were assessed as TRAEs. Patients in the PK subsample were treated with a higher initial dose (3000 mg/day) than other patients for the first two days and 5/14 (36%) of these patients experienced TRAEs. Three events of diarrhea, two events of vomiting, and two events of nausea were reported during the first two days of treatment with 1000 mg thrice daily. Five (6%) patients had treatment-emergent SAEs; none of these were assessed by Investigators as treatment-related. No deaths occurred during this study (**Table 2A**).

Physical Examination and Laboratory Assessments: There were no consistent changes in observed vital signs or relevant treatment-related changes in hematology or chemistry values over the course of the trial.

Patient Reported Outcomes: All 86 patients in the Safety Population completed the screening questionnaire and 80 patients completed the end-of-study visit questionnaire. At study entry, the median daily pretrial phosphate binder tablet intake was six tablets/day with 34% of patients taking ≥7 tablets/day (**Figure 2C**) and 58% of patients reporting consistent adherence to treatment (**Figure 3C**). At study end, the median daily tablet intake for OLC was

three tablets/day with 70% of patients reporting that they were consistently adherent to treatment (**Figure 3C**). More than three-quarters (79%) of respondents indicated that they preferred OLC over their pretrial phosphate binders (**Figure 3D**). More patients expressed satisfaction with OLC treatment (**Figure 3A**) and reported that OLC was easier to take than their previous phosphate binder (**Figure 3B**). More details from patient surveys are presented in Supplemental Figures 2 and 3.

Pharmacokinetics

For patients in the safety population, the mean plasma concentration of lanthanum before treatment was 0.079 ng/mL. Systemic absorption of lanthanum was minimal with a mean lanthanum concentration of 0.295 ng/mL at the end of titration and 0.277 ng/mL at the end of study visit. In the subset of 14 patients in the PK subsample there was minimal to no systemic absorption of lanthanum and serum concentrations were below the LLOQ in 72% of 112 samples. PK summary parameters are presented in **Table 3**.

DISCUSSION

The primary objective of this study was to assess the tolerability of clinically effective doses of OLC in patients on hemodialysis with hyperphosphatemia requiring phosphate lowering therapy. Tolerability was measured based on the rate of discontinuations due to TRAEs in the Evaluable Population during the Maintenance Period. Demographic and clinical characteristics of trial participants were typical of real-world patient populations in the US. At screening, the proportion of patients with sP ≤5.5 mg/dL was 59% and the distribution of sP was consistent with what has been previously reported.[1]

A total of five patients discontinued OLC treatment due to AEs. The low discontinuation rate (6%) in this study compares favorably to what has been reported in the package insert for the reference drug, lanthanum carbonate (Fosrenol®) (14%),[12] although the sample size in this trial was smaller.

Overall, OLC was generally well tolerated. As has been observed with other phosphate binders, [5,13] the most common TEAEs were gastrointestinal, including vomiting or diarrhea, which was typically transient and resolved despite continued OLC administration. It should be noted that three of eight patients who experienced treatment-related diarrhea, two of five patients who experienced vomiting, and two of the three patients who experienced nausea were patients in the PK subsample. Unlike those not participating in the PK substudy, who had the dose of OLC titrated up as needed from a starting dose of 500 mg three times a day (TID) or 1500 mg/day, patients in the PK study received an initial dose of OLC of 3000 mg/day for the first two days of treatment. These findings support the starting dose of OLC used in the non-PK participants of 500 mg three times daily.

Although efficacy was not formally evaluated, the ability of OLC to achieve the goal serum phosphate target was integral to determining whether patients were exposed to effective, clinically meaningful drug doses during the study, validating the tolerability findings. According to KDIGO recommendations,[3] the goal of phosphate lowering treatment is to reduce sP toward the population reference range (2.5–4.5 mg/dL); however, many clinicians adopt a less stringent target of 3.5–5.5 mg/dL.[2] Prior studies evaluating lanthanum carbonate used target serum phosphate concentrations <6.0 mg/dL.[14,15] Thus, the goal sP≤5.5 mg/dL selected for this study both encompassed prior threshold levels for lanthanum carbonate studies and aligned with = clinical practice.

More than 90% of OLC-treated patients achieved sP ≤5.5 mg/dL with a median dose of 1500 mg/day (three pills/day), which is substantially lower than the median number of pills required for the patients' previous phosphate binders (six pills/day). Observational data indicate that patients receiving in-center hemodialysis or peritoneal dialysis who achieve sustained control of sP experience more favorable clinical outcomes than those who do not. Despite the use of one or multiple phosphate binders, typically obligating ingestion of 9-12 or more tablets or capsules per day, the vast majority of patients on dialysis have sP consistently >4.5 mg/dL.[1,8,16] Some variability in sP control may be due to patient issues, including differences in enteral phosphate absorption, severity of secondary hyperparathyroidism, interindividual differences in phosphate binder efficacy, and the ability to comply with dietary restrictions or phosphate binder use.[17] Nearly 80% of patients on dialysis are unable to adhere to their prescribed dosing schedule of phosphate binder treatment.[18] This low adherence stems, at least in part, from the pill burden required for adequate phosphate binding.[19] In addition to the high number of pills needed per day, the need to take pills with meals, issues such as texture and taste with some oral phosphate binders, including lanthanum carbonate, which needs to be chewed completely before swallowing, and gastrointestinal adverse effects contribute to low or incomplete adherence to phosphate binder treatment.[18,20-24],

In an in vitro study comparing OLC with five commercially available phosphate binders, OLC was able to bind one gram of phosphate with the lowest daily dose volume and the smallest total volume.[10] These results support the contention that a more potent phosphate binder could lower sP with a lower pill burden, improving adherence to treatment and thus potentially leading to a more sustainable and effective therapy.

Regarding the pharmacokinetics of OLC, systemic exposure to lanthanum was low as has also been observed with lanthanum carbonate[25]. Most plasma samples were below the LLOQ for lanthanum, with no suggestion of accumulation over the course of the trial.

There were several strengths to this study. This was a multicenter trial using real-world clinical approaches to treatment, and, therefore, less likely to be influenced by practices or preferences of a single research location. Additionally, the population was broadly representative in terms of age, sex, self-reported race and ethnicity, and diabetes status and had been receiving commonly prescribed phosphate binders.

The limitations of this study must be clearly acknowledged. Most notably, the open-label, single-arm design without an active comparator weakens any formal conclusions regarding efficacy. While the regulatory pathway for OLC leverages existing data on lanthanum carbonate—thus not requiring further toxicity or efficacy studies relative to other phosphate binders—this regulatory context does not mitigate the need for rigorous comparative clinical evaluation in the setting of this study. Second, although the trial duration was short, clinicians and clinical investigators have expressed concern regarding risks of untreated hyperphosphatemia for periods longer than four to six weeks. Finally, questionnaires used to assess patient satisfaction in exploratory analyses were not formally validated.

In conclusion, in this single-arm, open-label trial conducted in patients receiving maintenance hemodialysis, we demonstrate that the phosphate binder oxylanthanum carbonate (OLC) was safe and well-tolerated, had low systemic absorption, and enabled control of sP in >90% of patients, with most requiring no more than one tablet with each meal.

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Supplemental Material List:

Screening Patient Satisfaction Questionnaire

End-of-Study Patient Satisfaction Questionnaire

Supplemental Figure 1. Study Design Diagram

Supplemental Figure 2. Satisfaction with Phosphate Binder Treatment

Supplemental Figure 3. Phosphate Binder is Easy to Take

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Figure Legends

Figure 1: CONSORT Diagram

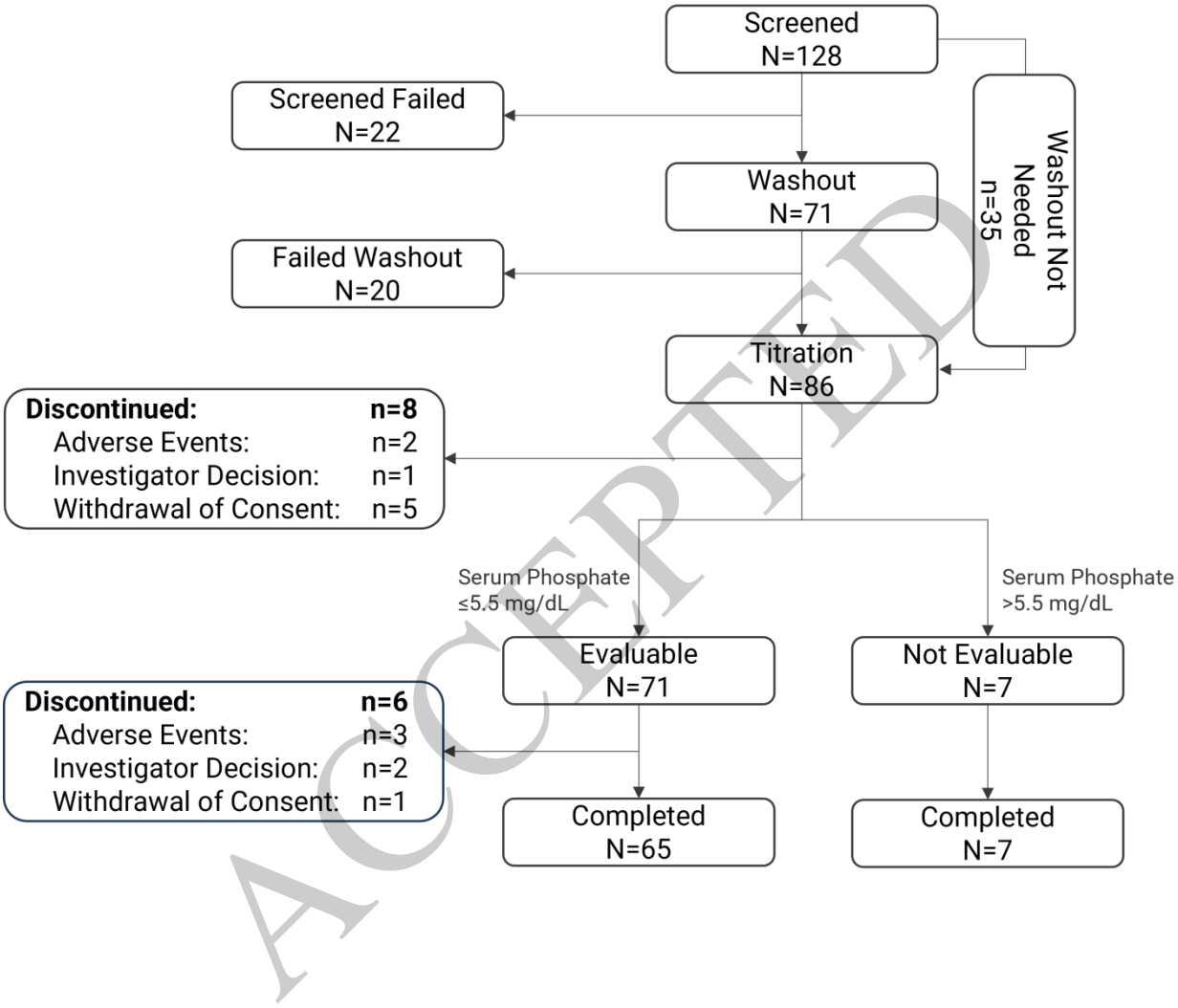

Figure 2: Serum Phosphate Control. (A) Doses Required for Phosphate Control (sP≤5.5 mg/dL) with Oxylanthanum Carbonate at End of Titration (N=71); includes patients whose serum phosphate was ≤5.5 mg/dL at their last visit during titration; (B) Phosphate Control at Baseline and at End of Titration; the baseline value was the last serum phosphate value prior to washout or prior to titration if their sP was >5.5 mg/dL during screening; (C) Patient-Reported Daily Phosphate Binder Pill Count; pill counts are from patient responses to satisfaction questionnaires (Supplemental Material).

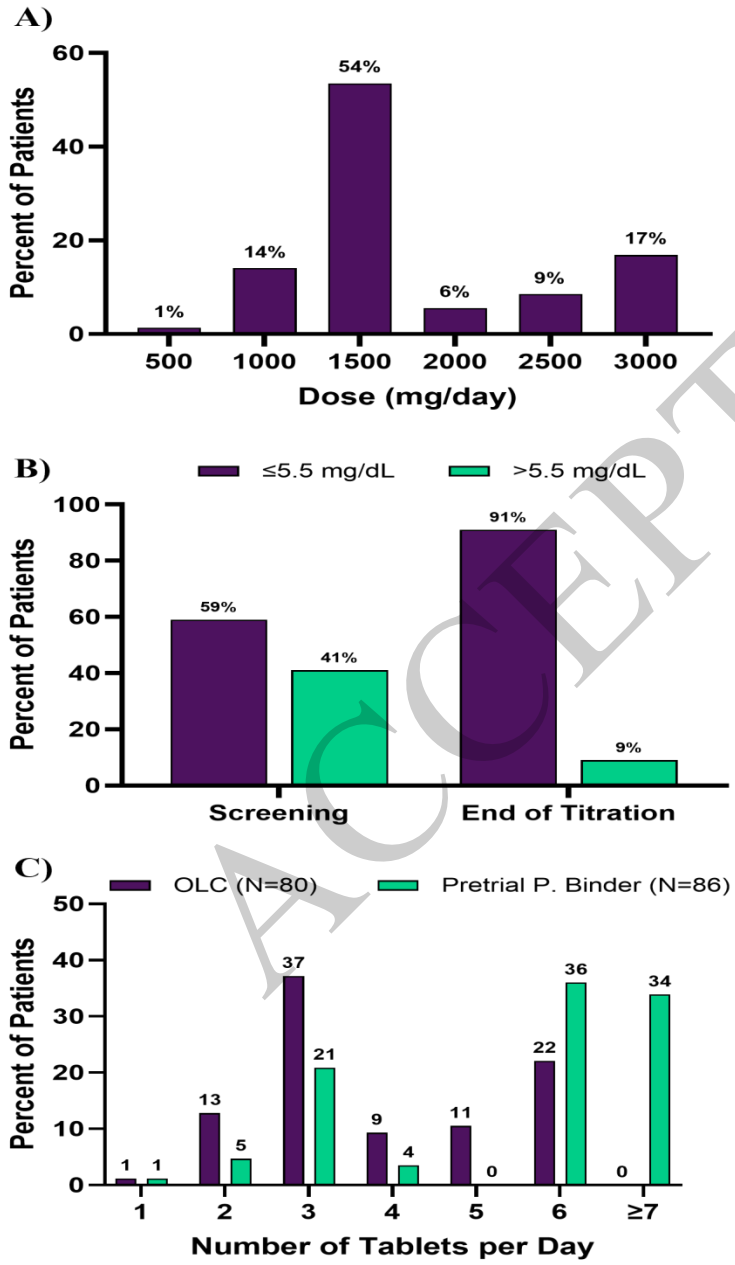

Figure 3: Patient Report Outcomes. Sample Patient Satisfaction Questionnaires are included in the Supplemental Material. PB, phosphate binder; OLC, oxylanthanum carbonate.

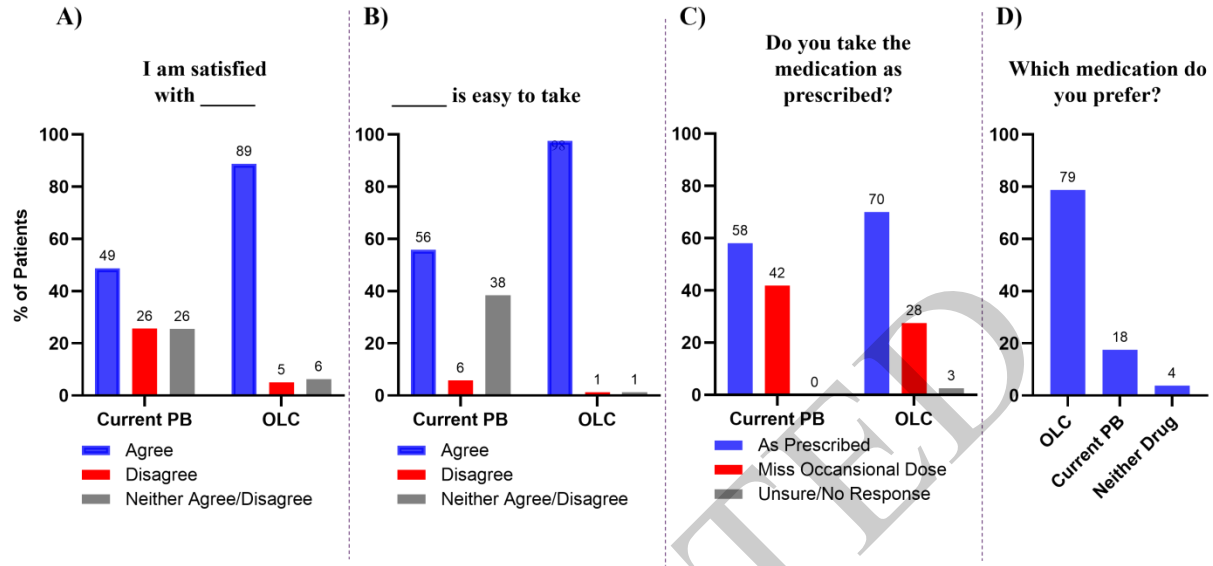

Table 1. Baseline Demographics

Characteristic	Safety Population (N=86)	Evaluable Population (N=71)	Pharmacokinetic Population (N=14)
Age (years)			
Mean (SD)	62.4 (10.71)	62.4 (10.22)	63.9 (10.71)
Median	63	63	63.0
Min, Max	29, 82	29, 82	47, 82
Sex, n (%)			
Female	39 (45)	35 (49)	8 (57)
Male	47 (55)	36 (51)	6 (43)
Race, n (%)			
American Indian or Alaska Native	8 (9)	7 (10)	0
Asian	1 (1)	0	0
Black or African American	18 (21)	16 (23)	1 (7)
Other	2 (2)	0	0
White	57 (66)	48 (68)	13 (93)
Ethnicity, n (%)			
Hispanic or Latino	34 (40)	28 (39)	13 (93)
Not Hispanic or Latino	52 (61)	43 (61)	1 (7)
Phosphate Binder, n (%) [a]			
Sevelamer	45 (52)	36 (51)	7 (50)
Calcium Acetate	17 (20)	11 (16)	0
Ferric Citrate	13 (15)	11 (16)	3 (21)
Sucroferric Oxyhydroxide	12 (14)	12 (17)	4 (29)
Tenapanor	1 (1)	1 (1)	0

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation.
a) Two patients had been taking two phosphate binding medications.

Table 2a. Overall Summary of Treatment-Emergent Adverse Events

	Safety Population (N=86) n (%)	Evaluable Population (N=71) n (%)
Patients with Treatment-Emergent Adverse Events (TEAEs)		
Patients with Any TEAE	30 (35)	22 (31)
Mild	16 (19)	11 (16)
Moderate	8 (9)	7 (10)
Severe	6 (7)	4 (6)
Patients with Treatment-Emergent SAEs	5 (6)	4 (6)
Patients with TEAEs Leading to Discontinuation	5 (6)	3 (4)
Patients with TEAE Leading to Death	0	0
Treatment-Related Adverse Events [a]		
Patients with any Treatment-Related AEs	15 (17)	9 (13)
Mild	8 (9)	5 (7)
Moderate	5 (6)	3 (4)
Severe	2 (2)	1 (1)
Patients Treatment-Related SAEs	0	0
Patients with Treatment-Related AEs Leading to Discontinuation	3 (4)	1 (1)

Abbreviations: AE = adverse event; SAE = serious adverse event; TEAE = treatment-emergent adverse event.
a) Related = related + possibly related as assessed by the Investigator

Table 2b. Summary of Adverse Events in at least two Patients (Safety Population)

	Treatment-Emergent Adverse Events (N=86) n (%)	Treatment-Related Adverse Events [a] (N=86) n (%)
Patients having at least one AE	30 (35)	15 (17)
Diarrhea	10 (12)	8 (9)
Vomiting	5 (6)	5 (6)
Constipation	3 (4)	3 (4)
Nausea	3 (4)	3 (4)
Abdominal distension	2 (2)	2 (2)

Abbreviations: AE = adverse event; TEAE = treatment-emergent adverse event.
a) Related = related + possibly related AEs as assessed by the Investigator

Table 3. Mean ± SD Pharmacokinetic Parameters of Lanthanum in Human Serum Following Oral Administration of OLC 1000 mg Thrice Daily

Parameter	Mean ± SD
C_{max} (ng/mL)	0.837 ± 1.02
T_{max} (hr) [Median (min-max)]	8.68 (0.00-25.9)
T_{last} (hr) [Median (min-max)]	16.9 (1.95-25.9)
AUC_{tlast} (hr·ng/mL)	15.0 ± NC[a]
AUC_{0-24} (hr·ng/mL)	21.1 ± NC[a]

Abbreviations: AUC_{0-24} = area under the concentration versus time curve from the start of dose administration to 24 hours postdose; AUC_{tlast} = area under the concentration-time curve from time 0 to the time of the final quantifiable sample; C_{max} = maximum observed concentration; hr = hours; max = maximum; min = minimum; NA = not calculated; OLC = oxylanthanum carbonate; SD = standard deviation; T_{last} = time of final quantifiable concentration; T_{max} = time of maximum observed sample concentration.

a) SD is not calculated when n < 3.

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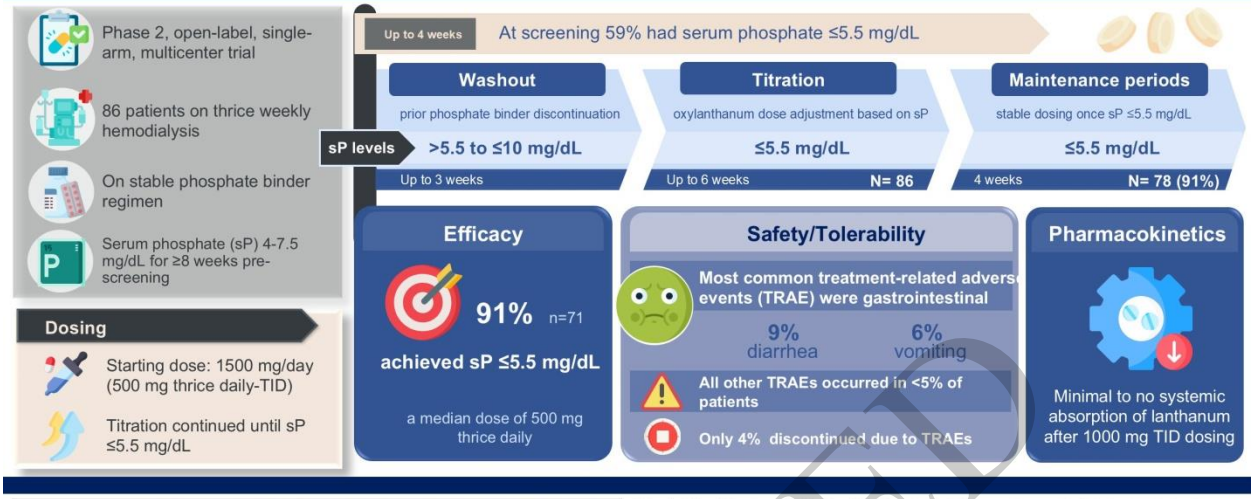

Conclusions: In this open-label, phase 2 trial, oxylanthanum carbonate was well tolerated and enabled serum phosphate control in more than 90% of patients with a low pill burden.

Block GA, Chertow GM, Reddy G, et al. ***Effects Phase 2 Clinical Trial of Oxylanthanum Carbonate in Patients Receiving Maintenance Hemodialysis with Hyperphosphatemia*** . CJASN. DOI 10.2215/CJN.0000000780

Visual abstract by Cristina Popa, MD

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