UNICYCIVE THERAPEUTICS INC.

NASDAQ: UNCY

Oxylanthanum Carbonate (OLC) UNI-OLC-201 Pivotal Trial Topline Data

June 25, 2024

Forward Looking Statements

This presentation contains certain "forward-looking" statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical or present facts, are forward-looking statements, including statements regarding our future financial condition, future revenues, projected costs, prospects, business strategy, and plans and objectives of management for future operations, including our plans for clinical trials and plans to submit for regulatory filings. In some cases, you can identify forward-looking statements by terminology such as "believe," "will," "may," "might," "estimate," "continue," "anticipate," "intend," "target," "project," "model," "should," "would," "plan," "expect," "predict," "could," "seek," "goal," "potential," or the negative of these terms or other similar terms or expressions that concern our expectations, strategy, plans, or intentions. These statements are based on our intentions, beliefs, projections, outlook, analyses, or current expectations using currently available information, and are not guarantees of future performance, and involve certain risks and uncertainties. Although we believe that the expectations reflected in these forward-looking statements are reasonable, we cannot assure you that our expectations will prove to be correct. Therefore, actual outcomes and results could materially differ from what is expressed, implied, or forecasted in these statements. Any differences could be caused by a number of factors including but not limited to: our expectations regarding the timing, costs, conduct, and outcome of our clinical trials, including statements regarding the timing of the initiation and availability of data from such trials; the timing and likelihood of regulatory filings and approvals for our product candidates; whether regulatory authorities determine that additional trials or data are necessary in order to obtain approval; our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates; our plans to research, develop, and commercialize our product candidates; the commercialization of our product candidates, if approved; the rate and degree of market acceptance of our product candidates; our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use, and the potential market opportunities for commercializing our product candidates; the success of competing therapies that are or may become available; our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; the ability to license additional intellectual property relating to our product candidates and to comply with our existing license agreements; our ability to maintain and establish relationships with third parties, such as contract research organizations, suppliers, and distributors; our ability to maintain and establish collaborators with development, regulatory, and commercialization expertise; our ability to attract and retain key scientific or management personnel; our ability to grow our organization and increase the size of our facilities to meet our anticipated growth; the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing; our expectations related to the use of our available cash; our ability to develop, acquire, and advance product candidates into, and successfully complete, clinical trials; the initiation, timing, progress, and results of future preclinical studies and developments and projections relating to our competitors and our industry. Topline data from the Oxylanthanum carbonate (OLC) pivotal trial is preliminary and subject to change based on further detailed analysis.

Additional factors that could cause actual results to differ materially from our expectations can be found in our Securities and Exchange Commission filings. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the effects of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. All forward-looking statements included in this presentation are expressly qualified in their entirety by these cautionary statements. The forward-looking statements speak only as of the date made and, other than as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

The company obtained the industry, market and competitive position data used throughout this presentation from its own internal estimates and research, as well as from industry and general publications, and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, the company's internal research and our industry experience, and are based on assumptions made by the company based on such data and its knowledge of the industry and market, which the company believes to be reasonable. In addition, while the company believes the industry, market and competitive position data included in this presentation is reliable and based on reasonable assumptions, the company has not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

Pivotal Clinical Trial (UNI-OLC-201)

Study Objective Achieved

- Demonstrated tolerability and safety of OLC in CKD patients on hemodialysis

Tolerability / Safety

- Total discontinuations due to adverse events were 5/86 (6%)
  - 3 treatment-related, 2 not related to treatment
- For reference*, Fosrenol® FDA package insert lists AE discontinuation rate at 14%
- Treatment related adverse events reported in ≥ 5% of patients were diarrhea (9%) and vomiting (6%)
- OLC safety profile compares favorably to Fosrenol and other phosphate binders on the market

Serum Phosphate Control

- 90% of OLC treated patients achieved effective serum phosphate control at the end of titration (n=86)
- 69% of patients controlled at OLC dose of ≤1,500 mg/day (n=71)

Implications

- We believe that these results for OLC will support the demonstration of similarity to Fosrenol with regard to tolerability and safety required for our 505(b)(2) NDA filing
- NDA filing next quarter (Q3, 2024)

*UNI-OLC-201 was not a comparator trial

UNICYCIVE
THERAPEUTICS INC.

OLC Background

Oxylanthanum carbonate (OLC) is an unapproved investigational new drug being developed under FDA's 505(b)(2) regulatory pathway. If approved, OLC will share substantially the same product label and prescribing information as the reference-listed drug (RLD) Fosrenol (lanthanum carbonate) with the exception that OLC tablets are smaller in size and swallowed whole with water and not chewed

Oxylanthanum Carbonate (OLC) Product Profile

Overview

- Potential **best-in-class product** being developed under **FDA's 505(b)(2) regulatory pathway** for the treatment of hyperphosphatemia
- If approved, OLC is expected to share substantially the same product label and prescribing information as the reference-listed drug Fosrenol (lanthanum carbonate)
- OLC advantages: (1) **Potency**: shares high phosphate binding capacity of lanthanum , (2) **Pill Burden**: smaller and fewer pills, (3) **Palatability**: swallowed whole with water and not chewed

Proprietary Nanoparticle Technology

- UNICYCIVE has harnessed the phosphate binding potency of lanthanum to reduce the number and size of pills that patients must take to control hyperphosphatemia
  - Enhanced surface area
  - Lower molecular weight
  - Immediate release tablets

  ›

  - Enables smaller pills
  - Pills are swallowed (not chewed)

Strong Global Intellectual Property

Recommended Daily Starting Dose for Phosphate Binders

MOST PRESCRIBED

Renvela®
sevelamer carbonate 800 mg

2 tablets 3 times per day, swallowed
Volume: 6.5 cm³

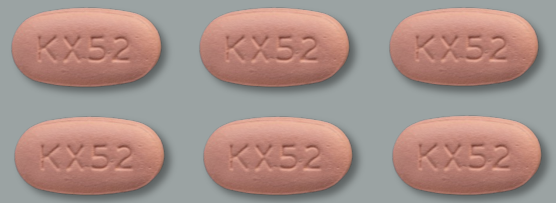
Oxylanthanum Carbonate (OLC)*
500 mg

1 tablet 3 times per day, swallowed
Volume: 1.15 cm³

Phoslo®
calcium acetate 667 mg

2 tablets 3 times per day, swallowed
Volume: 6.8 cm³

Auryxia®
ferric citrate 210 mg



2 tablets 3 times per day, swallowed
Volume: 5.5 cm³

Fosrenol®
lanthanum carbonate 500 mg

1 tablet 3 times per day, chewed
Volume: 4.0 cm³

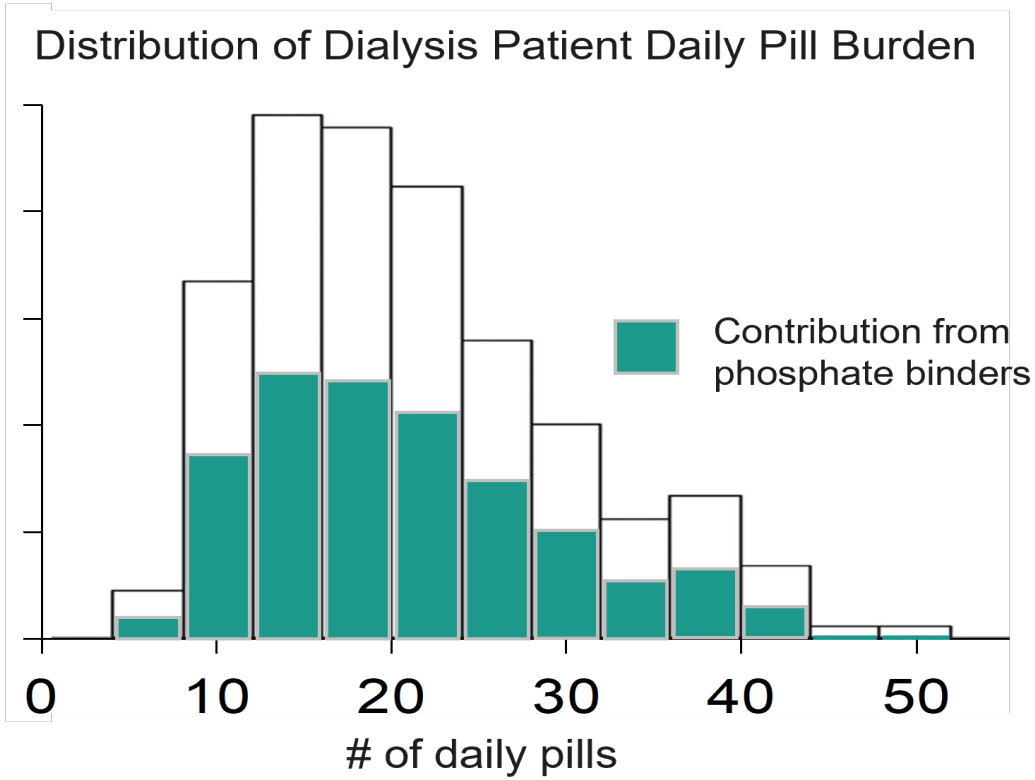
Velphoro®
sucroferric oxyhydroxide 500 mg

1 tablet three times per day, chewed
Volume: 5.5 cm³

Source: FDA approved package inserts, Pill volumes: Data on file, Unicycive Therapeutics, Product images are proportionally sized. Renvela® is a registered trademark of Sanofi., Auryxia® is a registered trademark of Akebia Therapeutics. | Fosrenol® is a trademark of Takeda Pharmaceutical Company Limited, Phoslo® and Velphoro® are registered trademarks of Vifor Fresenius

* Expected OLC recommended daily starting dose, if approved

Dialysis Patients Experience Excessive Pill Burden: Phosphate Binders Account for Half of the Problem



The daily pill burden for maintenance dialysis patients is among the highest across various chronic disease states including HIV/AIDS, diabetes mellitus, and congestive heart failure[1]

- **19** pills per day (median)
- **49%** of pill burden from phosphate binders
- Higher pill burden was independently associated with lower quality of life scores (HR-QOL)
- **62%** of patients are non-adherent (self-reported)

[1]Chiu YW, et al. Clin J Am Soc Nephrol. 2009

UNICYCIVE
THERAPEUTICS INC.

Regulatory Pathway

Studies to Support OLC NDA Filing

505(b)(2) Requirement	Studies Conducted*
☑ Demonstrate similar **Efficacy** to reference drug (Fosrenol)	Bridge to Efficacy → Bioequivalence Confirmed ← 1 OLC vs Fosrenol® Pharmacodynamic Bioequivalence Trial in Healthy Volunteers (Completed 12/2022)
☑ Demonstrate similar **Safety / Tolerability** to reference drug (Fosrenol)	Bridge to Safety/Tolerability → Some quantitative variability observed – additional study needed ← 2 OLC vs Fosrenol® Pre-Clinical Study (Completed 6/2023); Bridge to Safety/Tolerability → Favorable Tolerability Profile Confirmed ← 3 Pivotal Clinical Tolerability/Exposure Trial in Dialysis Patients (Completed 6/2024)

* All study designs agreed upon with FDA

UNICYCIVE
THERAPEUTICS INC.

Study Overview

UNI-OLC-201

Topline data from the Oxylanthanum carbonate (OLC) pivotal trial is preliminary and subject to change based on further detailed analysis.

Study Objective and Endpoints

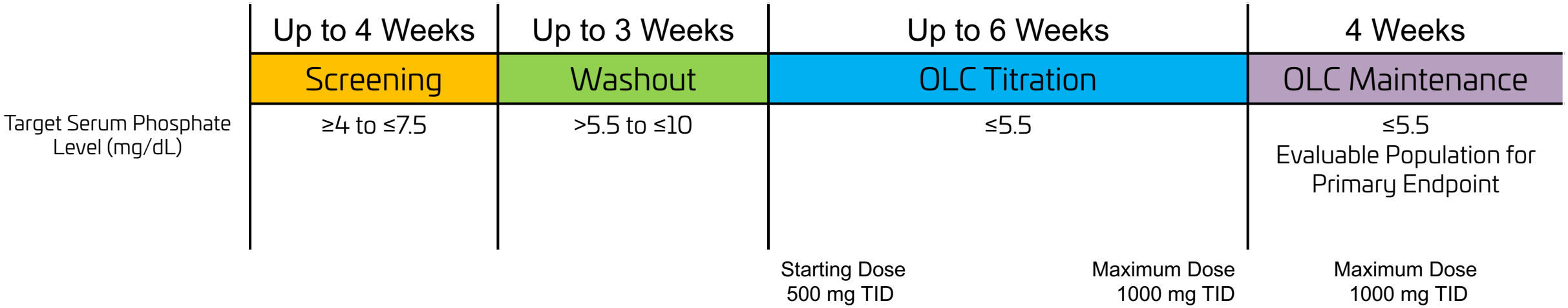
Study Objective:

To evaluate the tolerability of clinically effective doses (serum phosphate ≤5.5 mg/dL) of OLC in CKD patients on dialysis

Primary Endpoint	Secondary Endpoints
Tolerability: Tolerability is assessed based on the incidence of treatment-related adverse events leading to discontinuation from the study in the Evaluable Population	1) Safety: Safety is assessed based on the incidence of treatment-related adverse events 2) Pharmacokinetics: Pharmacokinetics of OLC

Pivotal Clinical Trial Design

Design, endpoints and sample size (n=60 evaluable) agreed on with the FDA



- **Washout Period:** Designed to clear existing binders from the circulation and ensure that serum phosphate was above 5.5 mg/dL
- **Washout Failure:** Those who had phosphate levels ≤5.5 mg/dL were considered wash out failures and excluded from the study.
- **Titration:** First 2 weeks of titration, all patients received 500 mg three times a day (TID) with meals. OLC was titrated every 2 weeks based on serum phosphate levels, up and down titration was allowed to a maximum dose 1000 mg TID.
- **Evaluable Patients:** Patients with serum phosphate levels ≤5.5 mg/dL and received at least one dose of OLC during maintenance.

Key Eligibility Criteria

Key Inclusion Criteria

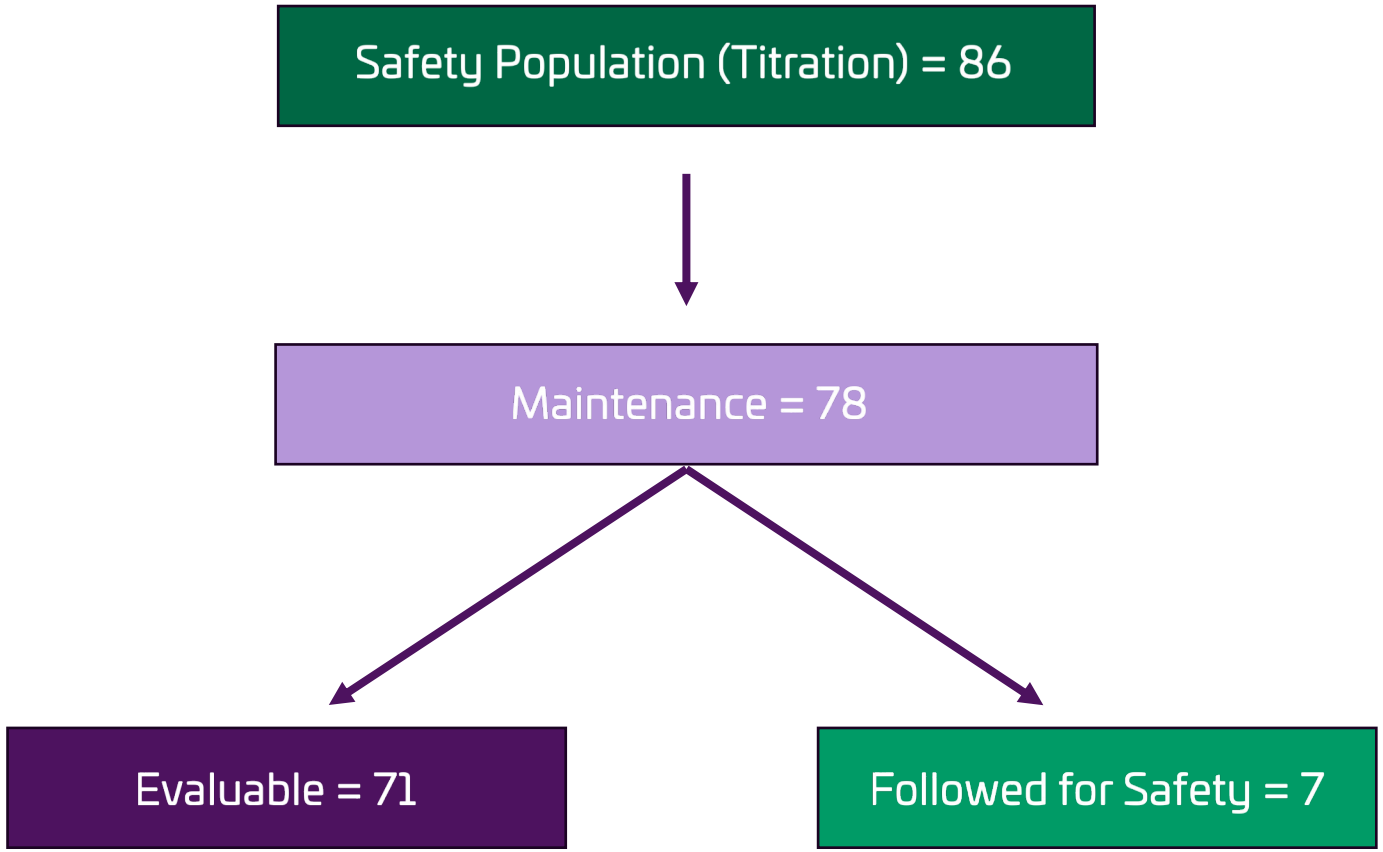
1. Patient must be ≥18 years of age.
2. Patient has stable chronic kidney disease and is undergoing and compliant with hemodialysis treatment 3 times per week for at least 12 weeks prior to screening
3. Patient has serum phosphate levels of ≥4.0 mg/dL and ≤7.5 mg/dL on phosphate binders for at least 8 weeks prior to screening
4. Patients with a Kt/V of ≥1.2 during the most recent monthly evaluation

Key Exclusion Criteria

1. Patient has had prior treatment with lanthanum-based binder (i.e., Fosrenol) within the past 6 months.

Enrollment Summary

- Safety Population: N=86 patients who entered titration and were treated with at least one dose of OLC
- Maintenance: n=78 were eligible to enter maintenance period
  - Evaluable Population: N=71 patients with serum phosphate ≤5.5 mg/dL at the end of titration and at least one dose in maintenance
  - 7 patients did not have target serum phosphate levels but followed for safety



Prior Phosphate Binder and Patient Demographics

Prior Phosphate Binder	n (%)
Renvela (sevelamer carbonate)	43 (50%)
Phoslo (calcium acetate)	17 (20%)
Auryxia (ferric citrate)	13 (15%
Velphoro (sucroferric oxyhydroxide)	12 (14%)
Other	1 (1%)

Patient Demographics	OLC (N=86) n (%)
Age (years)	
mean (SD)	62.4 (10.7)
Gender	
Female	39 (45.3)
Male	47 (54.7)
Ethnicity	
Caucasian	57 (66.3)
African American	18 (20.9)
American Indian or Alaska Native	8 (9.3)
Hispanic	2 (2.3)
Asian	1 (1.2)

UNICYCIVE
THERAPEUTICS INC.

Results:
Primary & Secondary Endpoints

UNI-OLC-201

Primary Endpoint: Tolerability

Rate of Discontinuation Due to Treatment-Related Adverse Events during the Maintenance Period (Evaluable Patients)

Total discontinuation due to AEs was 5/86 patients (6%)

Patient Population	n	Treatment-Related Discontinuations	Percent
Evaluable	71	1	1.4%
Safety	86	3	3.5%

Primary Endpoint: Tolerability

- OLC-201 is an open-label/non-comparator study design that was agreed upon with the FDA

- We believe that the low rate of OLC treatment-related discontinuations observed in this clinical trial compare favorably to the historical data that was submitted in the original Fosrenol NDA
  - Rate of discontinuations due to adverse events (treatment-related and non-treatment related) from Fosrenol Package Insert was 14%
  - OLC rate of discontinuations due to adverse events (treatment-related and non-treatment related) was 6%

We believe that these results for OLC are sufficient to support the demonstration of similarity to Fosrenol with regard to tolerability required for our 505(b)(2) NDA filing

Secondary Endpoints: Safety & PK

Treatment-Related Adverse Events in ≥5% Patients

Adverse Event	(N=86) n (%)
Diarrhea	8 (9%) [a]
Vomiting	5 (6%) [a]

a) Two patients experienced both diarrhea and vomiting

Safety

- No treatment-related Serious Adverse Events (SAEs)
- 6 patients had non-treatment-related SAEs
- Most AEs were mild-to-moderate; only 2 patients with severe treatment-related AEs

Pharmacokinetics

- PK assessment is ongoing and will be submitted in the NDA
- Prior Phase 1 clinical trial completed showed PK in healthy volunteers similar to Fosrenol

Adverse Event (AE) Profiles of Phosphate Lowering Therapies from FDA-Approved Product Labels

Fosrenol lanthanum carbonate		Renvela sevelamer carbonate		PhosLo calcium acetate		Velphoro sucroferric oxyhydroxide		Auryxia ferric citrate		Xphozah tenapanor	
Nausea	11%	Vomiting	22%	Hypercalcemia	13-16%	Diarrhea	24%	Diarrhea	21%	Diarrhea	43-53%
Vomiting	9%	Nausea	20%	Nausea	4-6%	Discolored feces	16%	Discolored feces	19%		
Abdominal pain	5%	Diarrhea	19%	Vomiting	2-4%	Nausea	10%	Nausea	11%		
		Dyspepsia	16%					Constipation	8%		
		Abdominal pain	9%					Vomiting	7%		
		Flatulence	8%					Cough	6%		
		Constipation	8%								

Disclaimer: FDA cautions that because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot to directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

We believe that the AE profile observed in the OLC pivotal trial compares favorably with the historical clinical experience with Fosrenol and other phosphate binders and supports a similar safety profile required for our 505(b)(2) NDA filing

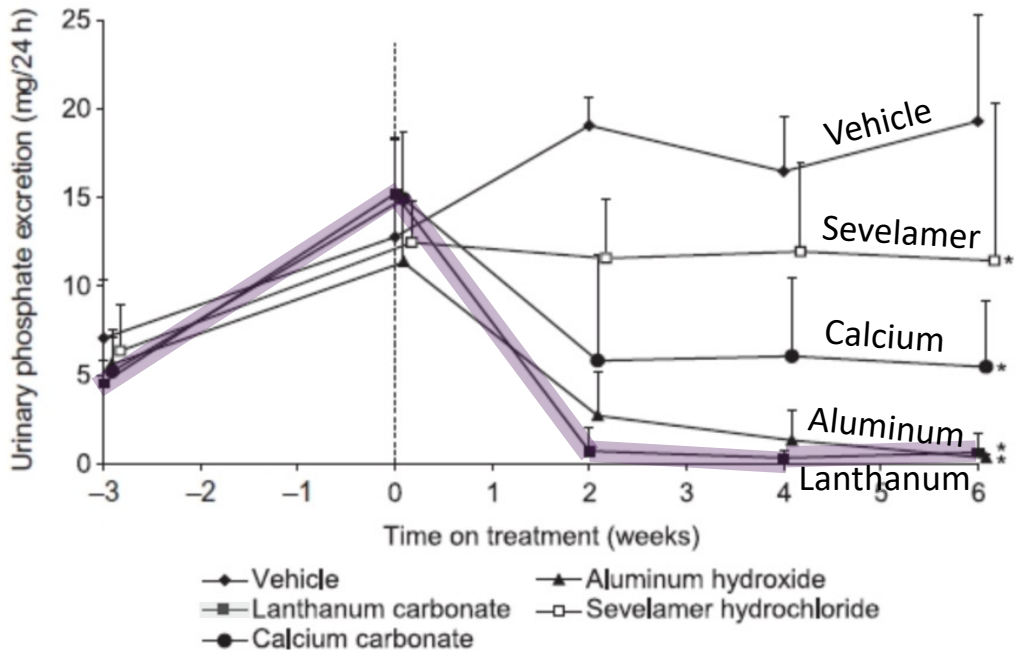
UNICYCIVE
THERAPEUTICS INC.

Serum Phosphate Control

UNI-OLC-201

Literature Reported Relative Phosphate Binder Potency

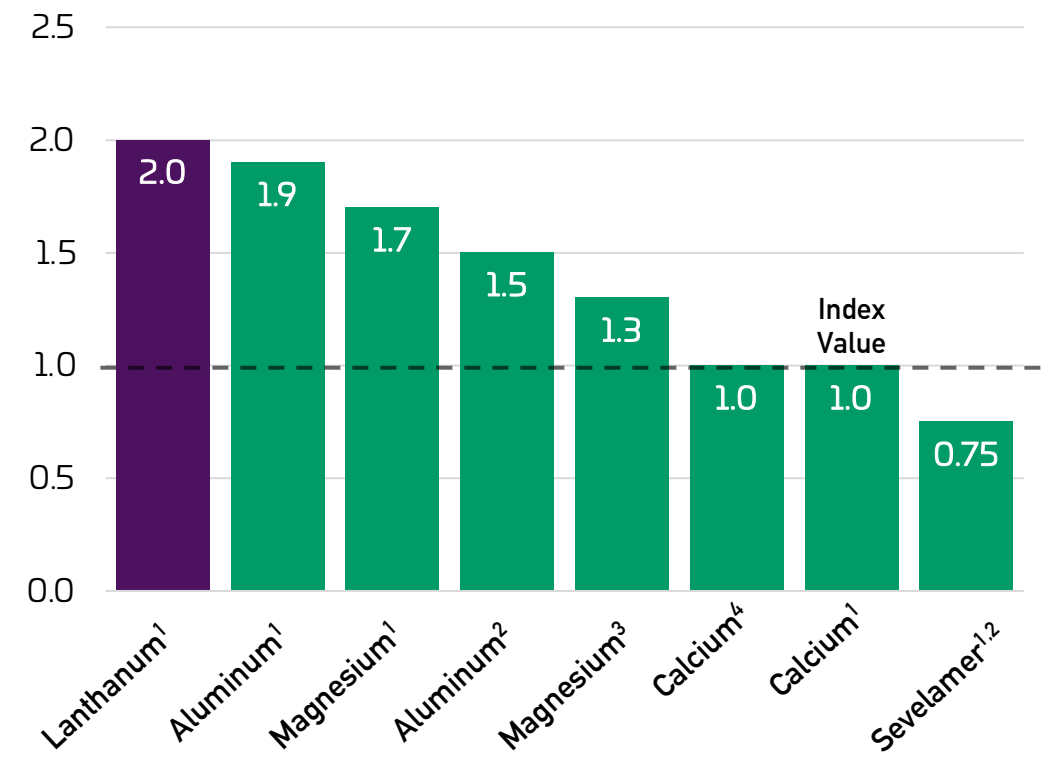
Relative urinary phosphate-lowering effect



Renal failure rat model (5/6 nephrectomy). All binders dosed at 1000 mg/kg/day.

Damment S. *Renal Failure.* 2011;33(2):217–224.

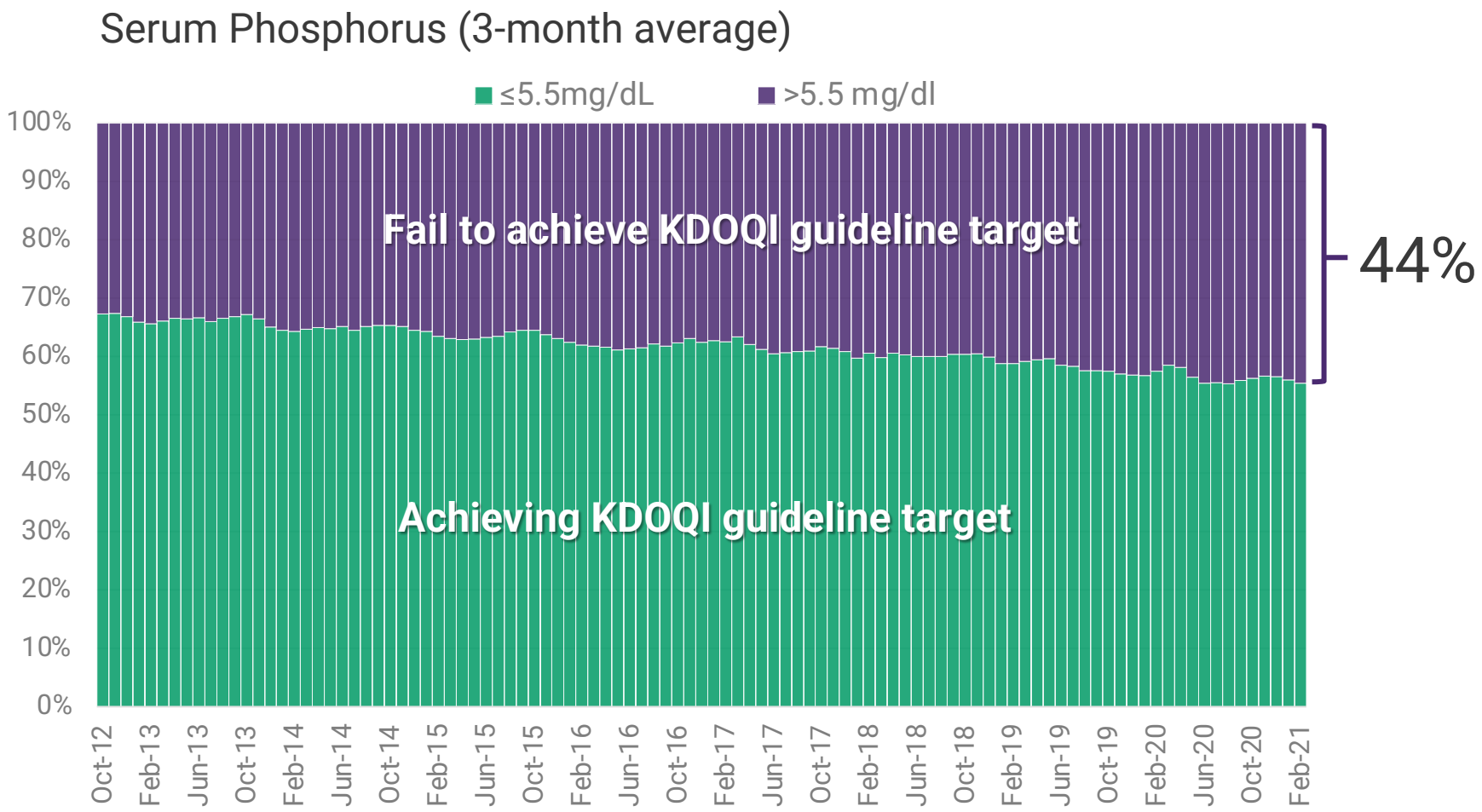
Relative phosphate-binding coefficient per gram of binder (calcium carbonate with an index value of 1.0)



[1] Carbonate, [2] hydroxide, [3] hydrate, [4] acetate.

Daugirdas JT, et al. *Seminars in Dialysis.* 2011;24(1):41–49.

Historical Phosphate Control Data from US-DOPPS Cohort

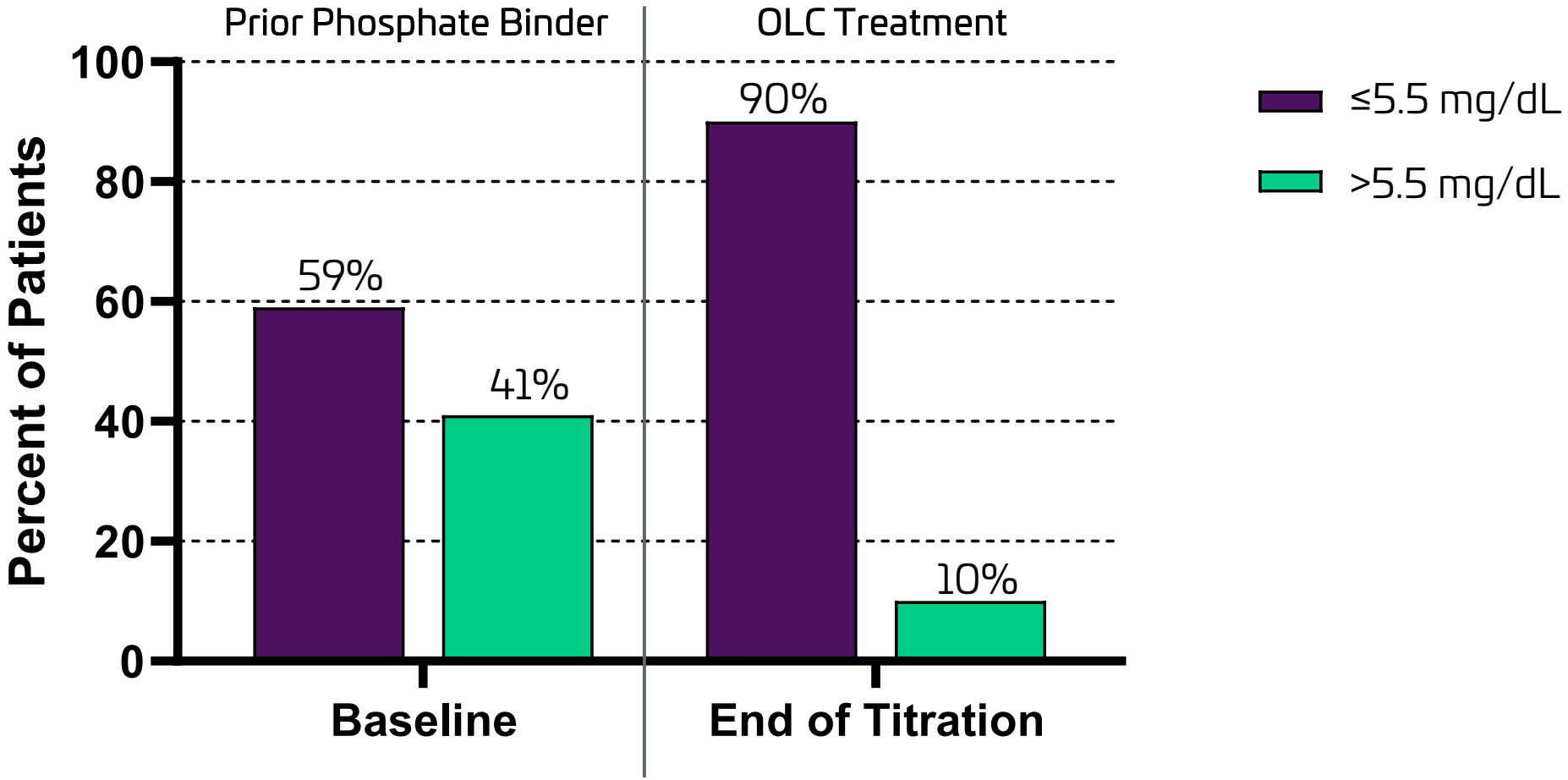


Source: US-DOPPS Practice Monitor, May 2021; http://www.dopps.org/DPM

The Dialysis Outcomes and Practice Patterns Study (DOPPS) is a prospective cohort study investigating practices related to the best outcomes for hemodialysis patients.

Dialysis data from a sample of over 11,000 patients in more than 200 US hemodialysis facilities.

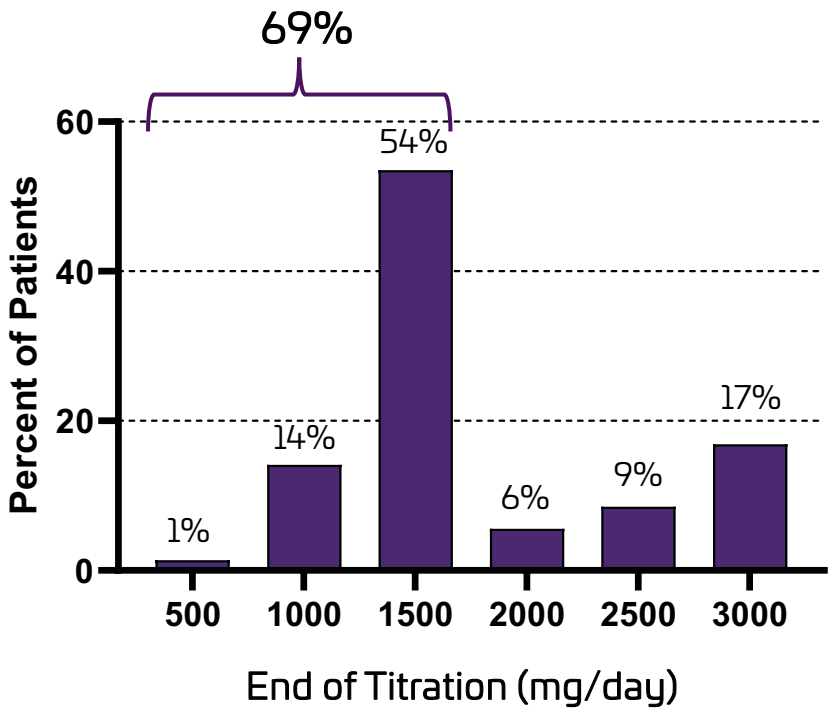
Phosphate Control in Safety Population (N=86) in UNI-OLC-201



Baseline - Serum phosphate levels at screening before washout
End of Titration – includes last serum phosphate levels from all patients including those that discontinued during titration 77/86 (90%) / 9/86 (10%)

Phosphate Control in Evaluable Population (n=71) in UNI-OLC-201

Of the 71 evaluable patients, 69% achieved a target serum phosphate level of ≤5.5 mg/dL at an OLC dose of ≤1500 mg/day



OLC Data Results Support NDA Filing

Achieved the Study Objective demonstrating tolerability and safety of OLC

Primary Endpoint: Tolerability

- Treatment-related discontinuation rate in Evaluable Population of **1.4%** (1/71)
- Total discontinuations due to adverse events were 5/86 (6%)
  - 3 treatment-related, 2 non-treatment related
  - For reference, discontinuation rate due to AEs from Fosrenol FDA package insert is 14%

Secondary Endpoint: Safety

- Diarrhea (9%) and vomiting (6%) occurred in ≥ 5% of patients; there were no treatment-related SAEs
- OLC safety profile compares favorably to Fosrenol and other phosphate binders on the market

Serum Phosphate Control

- OLC demonstrated 90% serum phosphate control during titration in the Safety Population
- At the end of titration, 69% achieved target levels at an OLC dose of ≤1500 mg/day

These encouraging results in hemodialysis patients validate our confidence in OLC's best-in-class potential and as an important new treatment option for patients with hyperphosphatemia, if approved.

UNICYCIVE
THERAPEUTICS INC.

Anticipated Milestones

OLC Expected Catalysts

- ✓ Successful bioequivalence study in healthy volunteers
- ✓ FDA alignment on regulatory path
- ✓ Completed enrollment in pivotal clinical trial
- ✓ Oral and Poster presentations at NKF & ERA (Q2 ‘24)
- ✓ Pivotal trial readout (Q2 ‘24)
- ❑ NDA Filing (Q3 ‘24)
- ❑ NDA Acceptance & PDUFA date designated by FDA
- ❑ Buildout of commercial infrastructure
- ❑ FDA Approval (mid-year ‘25)
- ❑ TDAPA Designation

Investor Relations

T: (650) 900-5470

ir@unicycive.com

UNICYCIVE
THERAPEUTICS INC.