UNICYCIVE
THERAPEUTICS INC.
NASDAQ: UNCY

Novel Treatments for Kidney Disease

Company Presentation

January 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 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.

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.


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Investment Thesis

Additional $100 Million in Committed Capital in 3 Tranches of Warrants

The Opportunity

- New Drug Application (NDA) filing expected mid-year 2024
- Near-term commercial opportunity in a large, unsatisfied market
- Potential Best-in-class product with strong IP protection
- Seasoned management team with a winning track record in the market for their 1st product
- Favorable Medicare reimbursement offering unrestricted product access with unnegotiated pricing through a special TDAPA (transitional drug add-on payment adjustment) program

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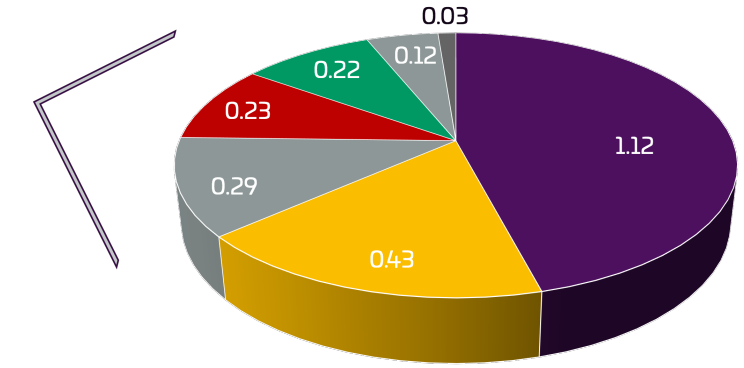
Oxylanthanum Carbonate (OLC) for the Treatment of Hyperphosphatemia in Chronic Kidney Disease (CKD) Patients on Dialysis

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

Global Hyperphosphatemia Market Opportunity

2.46
Billions of USD
(2021)

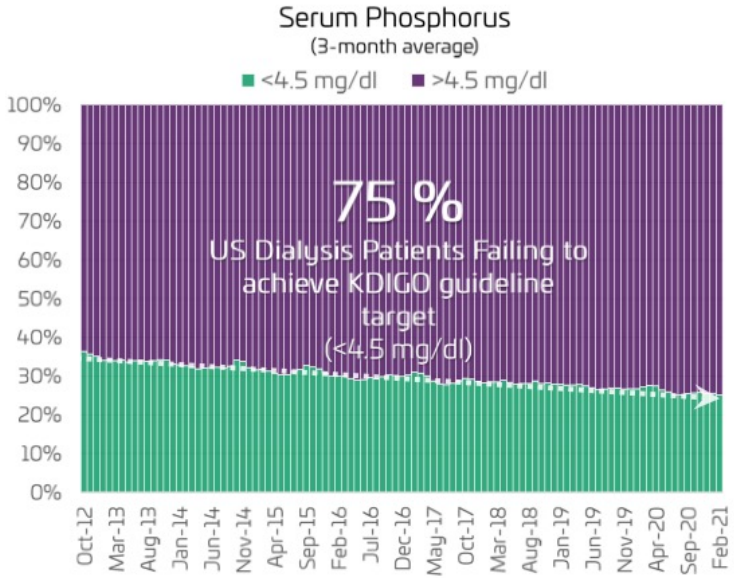


5.3% CAGR
in the forecast period
2021-2028

- US and international markets are highly genericized, market potential is dramatically greater at branded pricing
- OLC partnered in China, S Korea, and additional Asian markets

Source: Fortune Business Insights™, *Hyperphosphatemia Treatment Market, 2021-2028*

The Unmet Need in Hyperphosphatemia

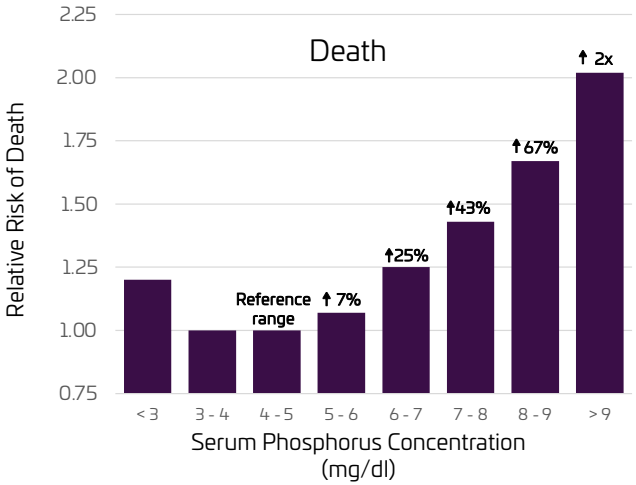


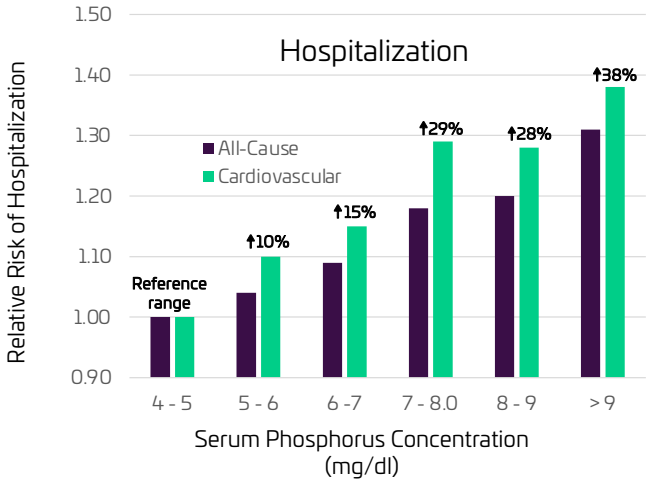
Hyperphosphatemia (abnormally high serum phosphate levels) is prevalent and remains uncontrolled[1]

- Occurs in at least 80% of patients with Stage 5 CKD on dialysis (>500,000 patients in the US)
- Despite the availability of 6 FDA-approved phosphate binders, hyperphosphatemia remains uncontrolled in an estimated 75% of US dialysis patients.[1]

[1]US-DOPPS (Dialysis Outcomes and Practice Patterns Study), May 2021; http://www.dopps.org/DPM

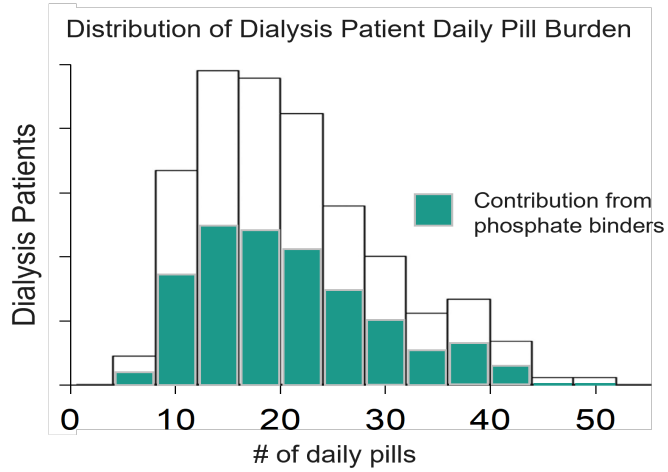
Uncontrolled Hyperphosphatemia is Strongly Associated with Mortality and Hospitalization





Mineral Metabolism, Mortality, and Morbidity in Maintenance Hemodialysis | Geoffrey A. Block, Preston S. Klassen, J. Michael Lazarus, Norma Ofsthun, Edmund G. Lowrie and Glenn M. Chertow | JASN August 2004, 15 (8) 2208-2218; DOI: https://doi.org/10.1097/01.ASN.0000133041.27682.A2

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)

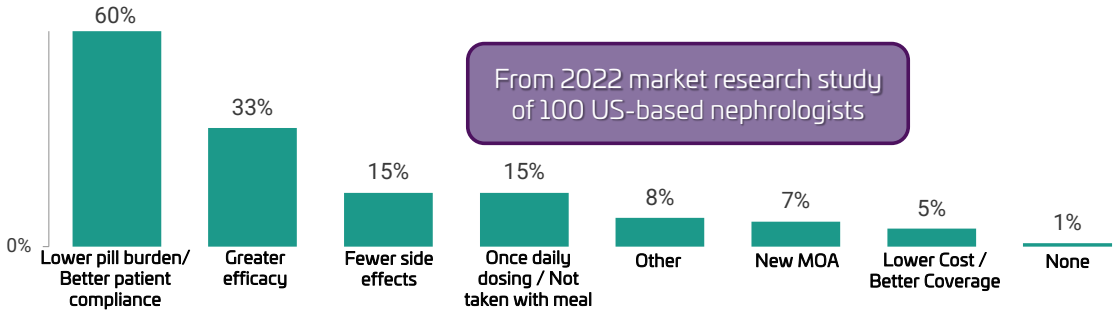
[1]Chiu YW, et al. Clin J Am Soc Nephrol. 2009

Current Treatments are Inadequate: High Pill Burden is the Chief Culprit

Juergen Floege, MD,
Nephrologist,
Executive Committee Member,
KDIGO CKD-MBD Guidelines
June 2020

*"Ideally, we would have phosphate binders with high phosphate-binding capacity (translating into low pill burden and good patient adherence)…**we still do not have such a phosphate binder.**"*[1]

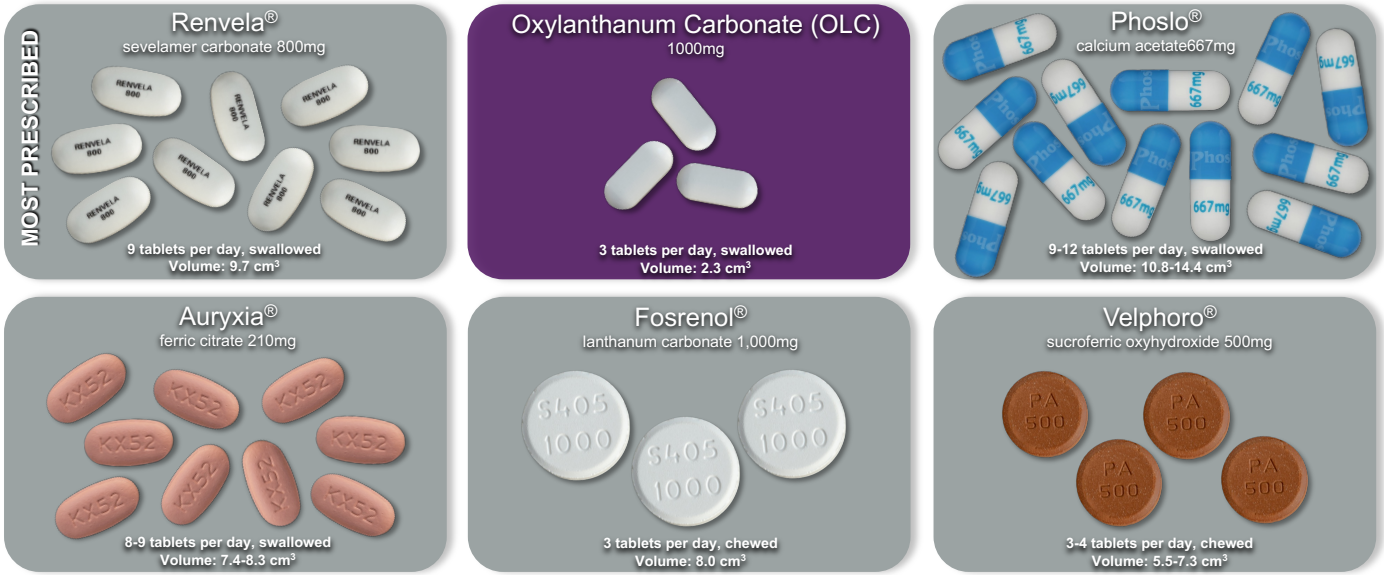
Greatest Unmet Need in Treatment of Hyperphosphatemia with Phosphate Binders (Unaided)



Question: *What is the greatest unmet need in the treatment of hyperphosphatemia with phosphate binders?*

[1]*Phosphate binders in chronic kidney disease: an updated narrative review of recent data,* J Nephrol. 2020 Jun;33(3):497-508 | Primary Market Research: OLC Conjoint Study, March 2022

OLC May Reduce Daily Pill Burden Volume by More Than 4-Fold Compared to the Most Prescribed Phosphate Binder



Source: Average daily dose: **dailymed.nlm.nih.gov**, 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

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 will share substantially the same product label and prescribing information as the reference-listed drug Fosrenol (lanthanum carbonate)
- OLC tablet advantage: 1) smaller in size and (2) are 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

- A family of patents (including composition of matter) were filed in 2011 for the U.S with exclusivity until 2031
- Corresponding patents granted in Canada, Europe, Japan, China, Australia, and other countries with 2031 expiry

Phase 1 Clinical Trial: OLC was Well-Tolerated with Dose-Dependent Phosphate Lowering Effect

Study Design:

Open label, dose ranging study (evaluated 4 OLC doses: 1500, 3000, 4500 and 6000 mg/day)

Endpoint: Phosphorus binding capacity

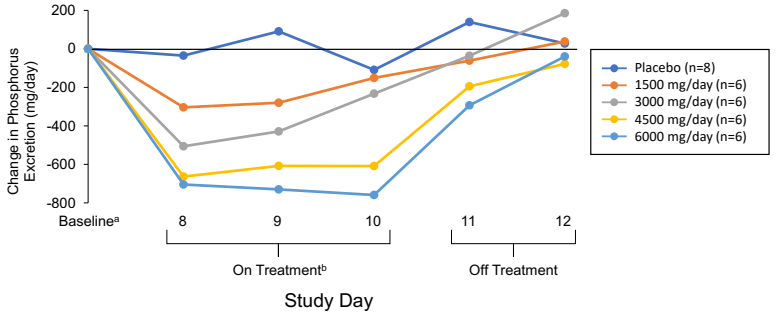
OLC showed statistically significant ($p<0.001$) phosphate reduction with all four doses:

- ✓ 1500 mg/day (-244.9 mg/day)
- ✓ 3000 mg/day (-421.0 mg/day)
- ✓ 4500 mg/day (-633.6 mg/day)
- ✓ 6000 mg/day (-713.7 mg/day)

Drug Safety

- All treatment-related adverse events (AEs) were mild in severity
- No severe or life-threatening AEs reported

Urine Phosphate Concentration Change from Baseline[1]
(n=32 Healthy Volunteers)
mg/day, Urine Phosphate



[1]Baseline is the mean of phosphate concentrations from study day 2 to day 6
Note: Urine phosphate concentrations for each day is recorded on the morning of the following day at a 24-hour interval | SOURCE:SPI-RZB-11-101 CSR

Key Clinical Study Establishes Bioequivalence of OLC to Reference-Listed Drug, Fosrenol®

Summary of Mean Change in Urinary Phosphorus Excretion (mg/day)

Visit	Statistics	OLC	Fosrenol
	N	75	75
Baseline	LS Mean (SE)	861.6 (30.9)	876.1 (30.9)
Evaluation Period	LS Mean (SE)	546.7 (19.4)	546.8 (19.4)
Change	LS Mean Change (SE)	-320.4 (17.7)	-324.0 (17.7)
	90% CI for LS Mean Treatment difference		-37.8, +45.1
	Acceptance Range		-64.8, +64.8

- FDA requirement is to establish similarity of the primary endpoint (least-squares mean change from baseline) within a ± 20% range to Fosrenol (the reference-listed comparator)
- Bioequivalence study results satisfy FDA's requirement and provide a bridge to clinical efficacy to support 505(b)2) NDA filing

Pivotal Clinical Study of OLC in Dialysis Patients to Evaluate Tolerability and Exposure

Primary Endpoint:

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

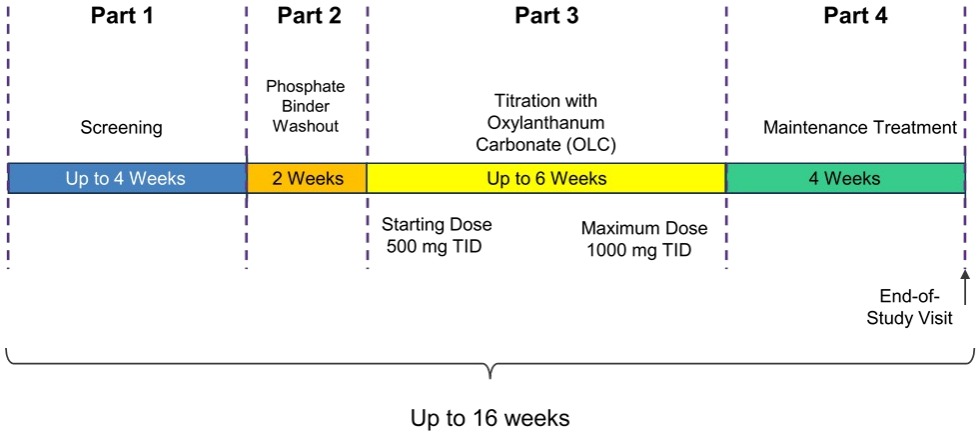
Secondary Endpoint:

Safety & PK

Sample Size:

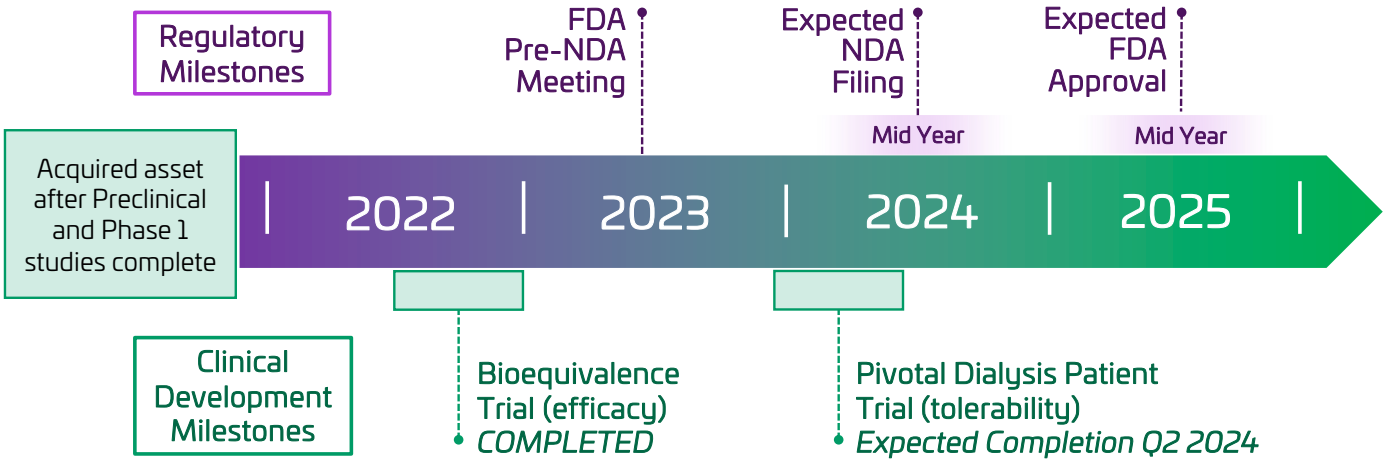
60 evaluable patients

Study Design

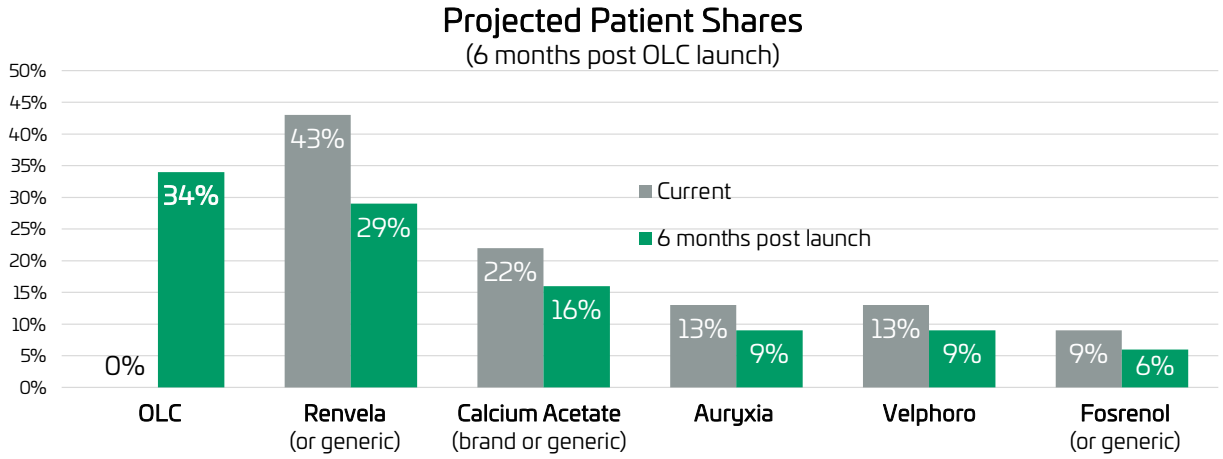


Study ongoing with topline results expected mid-2024

OLC Development Timeline



OLC's Best-in-Class Profile is Projected to Command a High Preference Share of Patients



Base: n=100 Nephrologists, Question: *Assuming Binder X (OLC) were 6 months post-launch with cost and coverage similar to Velphoro and Auryxia, how, if at all, would your prescribing change among your patients who are receiving a phosphate binder?*

Source: OLC Conjoint Market Research Study, Reason Research, March 2022

OLC Commercial Strategy

Commercial planning underway to leverage large market opportunity

- Product positioning, market access, and market shaping activities ongoing to establish best-in-class value proposition
- Key Opinion Leader (KOL) engagement activities ongoing
- Deployment of purpose-built commercial model to maximize awareness, demand generation and market access for the launch of OLC
  - Concentrated universe of phosphate binder prescribers allows for cost-efficient targeting with relatively small commercial footprint
- Capitalize on CMS plan to expand patient access to phosphate binders in 2025
  - Two years of separate Medicare Part B payment (Transitional Drug Add-On Payment Adjustment – TDAPA) for new drugs at 100% of average selling price (ASP)

Oxylanthanum Carbonate (OLC)
IP Status

Strong Global Intellectual Property

- A family of patents (including composition of matter) were filed in 2011 for the U.S with exclusivity until 2031
- Corresponding patents granted in Canada, Europe, Japan, China, Australia, and other countries also have 2031 expiry
- Potential patent term extension through 2035

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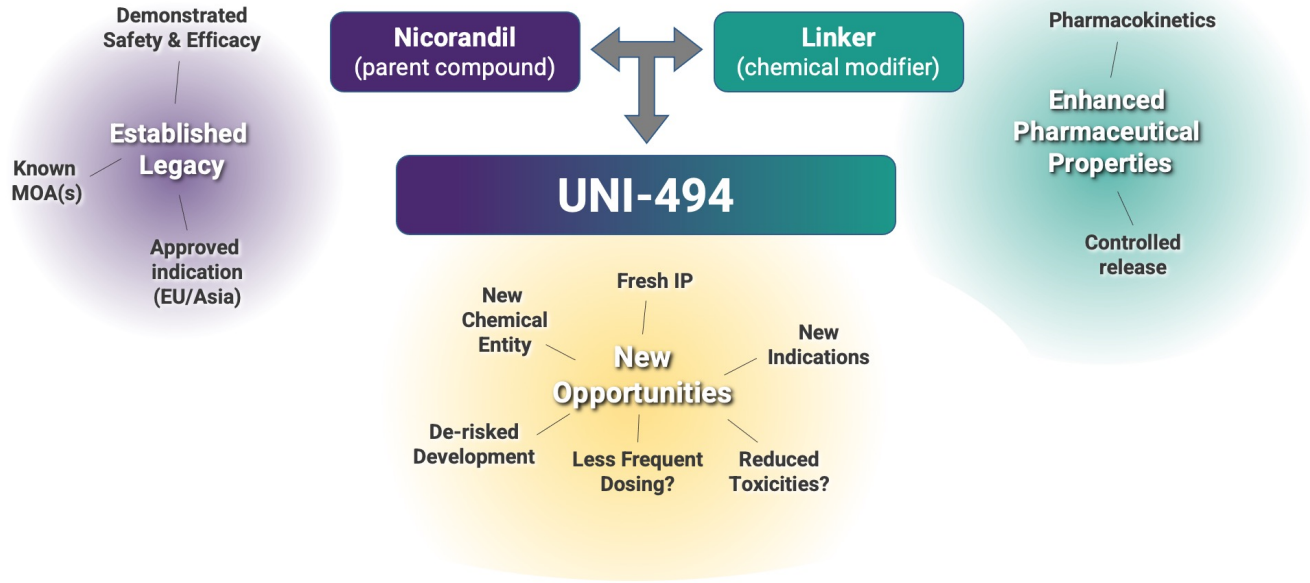
UNI-494: Mitochondrial-Targeted Therapy for Kidney Disease

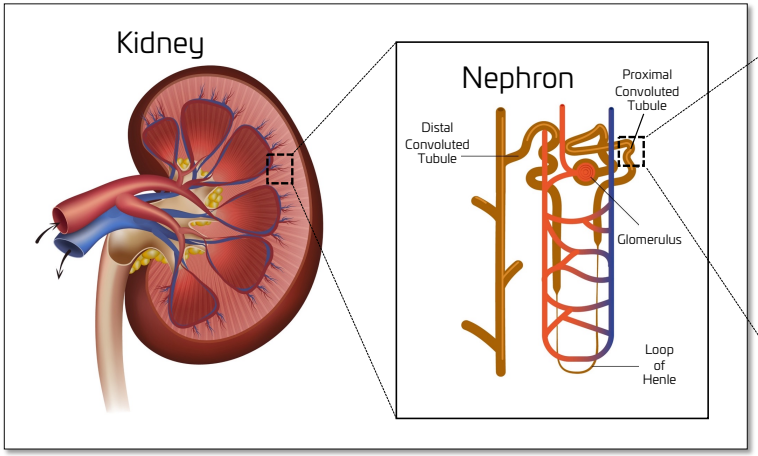
UNI-494 Profile

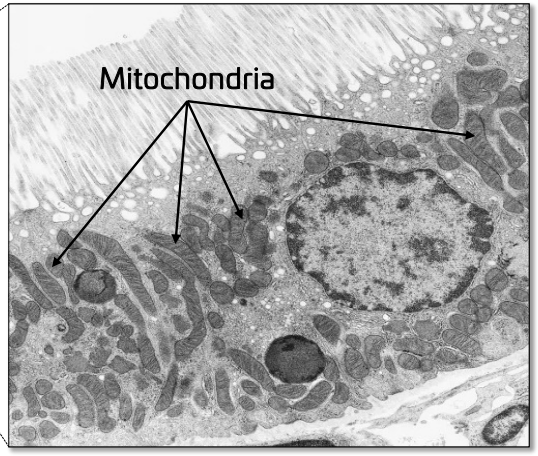


Due to its High Energy Demands, the Kidney is a Prime Target for Mitochondrial Injury

"The kidney constitutes 1% of body weight but utilizes 10% of total body oxygen consumption."[1]

"The proximal tubule is the primary target of injury and progression of kidney disease."[1]

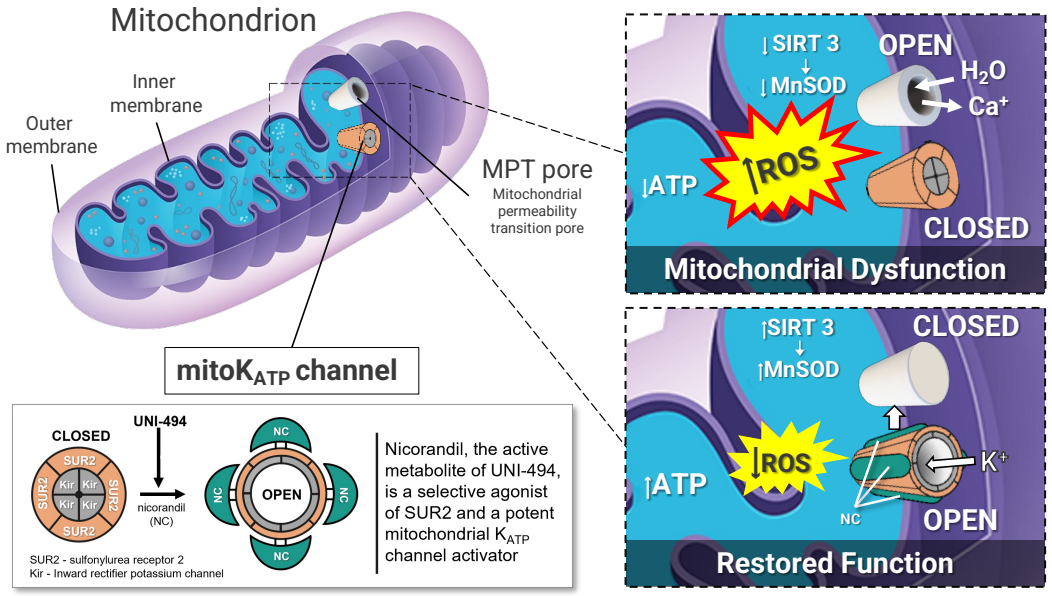




Transmission Electron Micrograph of Proximal Tubule
Brenner and Rector's The Kidney, 8th ed.

[1]Am J Physiol Renal Physiol. 2016 Jul 1; 311(1): F145-F161

UNI-494 Restores Mitochondrial Function
Mechanism of Action



- A hallmark feature of mitochondrial dysfunction is chronic opening of MPT pores and overproduction of reactive oxygen species (ROS)
- Chronic opening of MPT pores leads to water and solute influx, swelling, injury and cell death

- UNI-494 is an ATP-sensitive K^+ channel (KATP) activator
- Binds to SUR2 subunit of KATP channel that in turn leads to closing of MPT pores
- Down-regulates production of ROS

Source: Hazel H Szeto J Am Soc Nephrol 28: 2865, 2017; Shiraishi et al., 2014

Nicorandil: Clinical Evidence for Renoprotection

Clinical Setting	Outcome	Ref
Acute Kidney Injury		
Patients with poor kidney function scheduled for PCI (n=213) randomized to saline or nicorandil	• Dose: 0.096 mg/mL cont. infusion; 4 hours before and 24 hours after PCI • Significant reduction in contrast-induced nephropathy (2.0% vs 10.7%, p <0.02) • Reduction in contrast-induced increase in sCr and cystatin C • Control arm showed significant decline in eGFR (-4.2% vs +2.1%; p<0.001), @ 1 month	**Nawa et al., 2015**
At-risk patients scheduled for PCI (n=128) randomized to placebo or nicorandil	• Dose: 10 mg/day; 30 mins before to 3 days after PCI • Significant reduction in contrast-induced nephropathy (4.7% vs 21.9%, p <0.008) • No change in eGFR from baseline, significant decline in eGFR in control arm)	**Iranirad et al., 2017**

Clinical Setting	Outcome	Ref
Chronic Kidney Disease		
Proteinuric patients (n=136) randomized to placebo, ISDN or nicorandil for 6 months	• Dose 15 mg/day for 6 months • Significant (44%) reduction in proteinuria (p < 0.0001); • Significant reduction in urinary endothelin-1 excretion	**Lee & Chang, 2009**
Hemodialysis patients (n=129) who underwent PCI and were randomized to chronic placebo or nicorandil	• Dose 15 mg/day • Significant improvement in 3-year all-cause survival (79% vs 61%) (p= 0.01) • Significant improvement in 3-year cardiac death-free survival (87% vs 71%) (p=0.009)	**Nishimura et al., 2009**

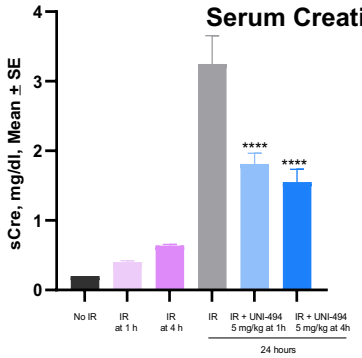
In a metanalysis of 7 Randomized Controlled Studies (N=1532), nicorandil decreased the incidence of CIN by 69% (OR: 0.31 95% CI: 0.20-0.46) Pranata et al, 2020.

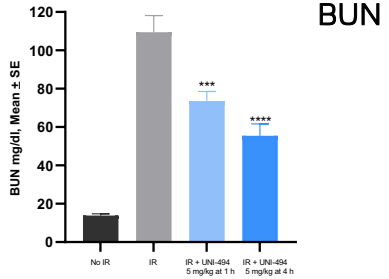
UNI-494 Exhibits Significant Efficacy in Animal Models

UNI-494 Reduces Biomarkers of Kidney Function

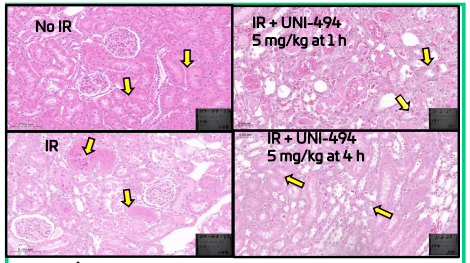
Summary:

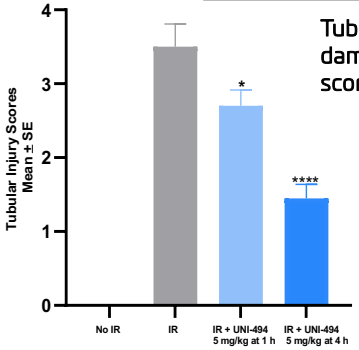
- Ischemia induced for 30 minutes in rat models
- UNI-494 dosed 1 or 4 hours after Ischemia
- UNI-494 reduces sCr, BUN, ACR and kidney tubule damage scores significantly





UNI-494 Reduces Tubular damage scores





*p = 0.05; **p = 0.01; ****p = 0.0001 when compared to No IR group; Arrows pointed to proximal tubule; Tubular Scores as per Jablonski et al 1983

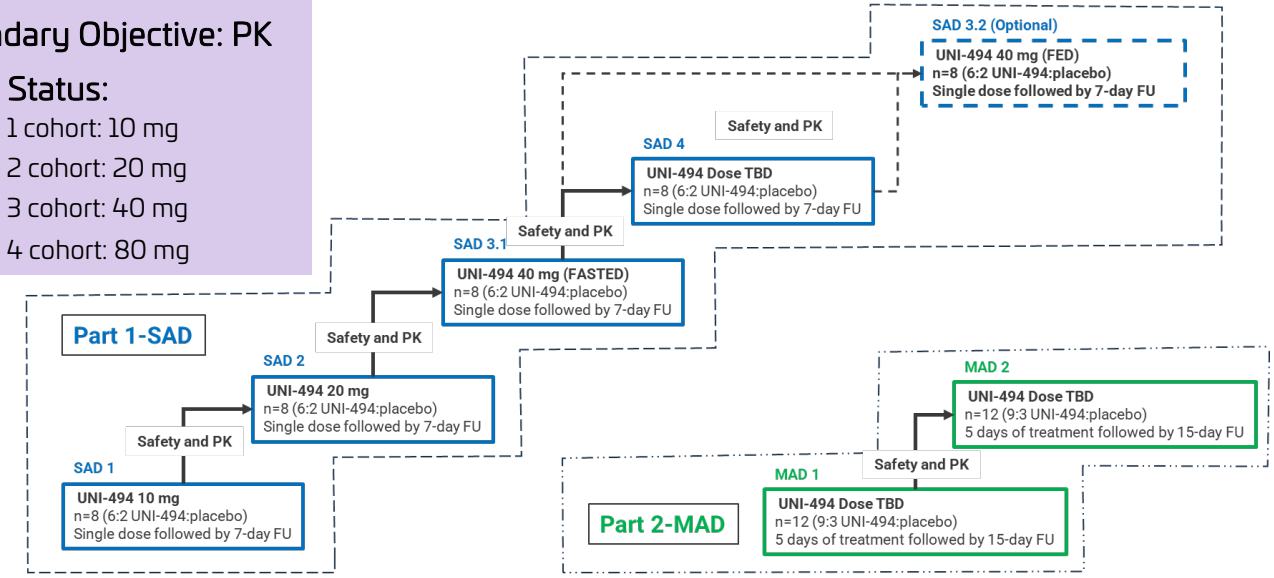
UNI-494 Phase 1 Study Design & Status

Primary Objective: Safety

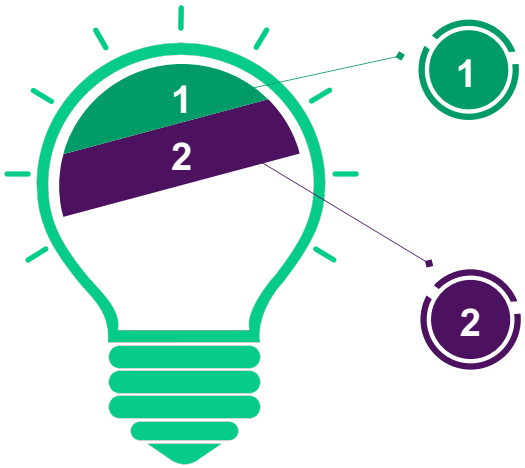
Secondary Objective: PK

Study Status:

- ✓SAD 1 cohort: 10 mg
- ✓SAD 2 cohort: 20 mg
- ✓SAD 3 cohort: 40 mg
- ✓SAD 4 cohort: 80 mg



UNI-494 Global Intellectual Property



UNI-494 is protected by a broad issued patent

- Patent granted in the U.S. and Europe with expiry 2032
- Patent pending in Japan and China
- Exclusively licensed to Unicycive

Additional patents filed for UNI-494 in the U.S. and globally

- If granted, would expire 2040
- International patent applications planned from this patent family
- Additional multiple patent applications being filed

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Corporate Overview

Seasoned Management Team With Winning Track Record in Hyperphosphatemia Market

Management

Shalabh Gupta, MD
Chief Executive Officer
NYU Medical Center, Genentech, UBS, HC Wainwright

John Townsend, CPA
Chief Financial Officer
Guardion Health Sciences, Cytori Therapeutics

Doug Jermasek, MBA
EVP, Corporate Strategy
Genzyme-Sanofi, Akebia, Keryx, Pfizer, Abbott

Pramod Gupta, PhD
EVP, Pharmaceutical & Business Operations
Spectrum, B&L, Abbott

Guru Reddy, PhD
VP, Preclinical R&D
Spectrum, Ciphergen, Pangene, Yale

- Led Genzyme/Sanofi global renal business that grew Renvela (sevelamer) to a $ billion+ franchise
- Led commercial team at Keryx that doubled Auryxia year/year revenues for 4 consecutive years
- Led preclinical/clinical and manufacturing development of oxylanthanum carbonate at Spectrum
- Responsible for the successful filing of multiple NDAs

Unicycive Directors & Advisors

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Formerly Vivo Capital

Sara Kenkare-Mitra, PhD
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Alector

Sandeep "Steve" Laumas, MD
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North Sound Capital

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Wyeth, Merck,
Kadmon

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Stanford University School of
Medicine

Myles Wolf, MD
Charles Johnson, Prof of
Medicine and Chief, Division
of Nephrology at Duke
University School of Medicine

Catalyst Rich 2024 and Beyond

OLC

- ✓ Successful bioequivalence study in healthy volunteers
- ✓ FDA alignment on regulatory path
- ✓ Initiated Pivotal clinical trial
- ❑ Pivotal trial readout (Q2 2024)
- ❑ NDA Filing (mid-year 2024)
- ❑ Buildout of commercial infrastructure

UNI-494

- ✓ Initiated Phase 1 clinical trial
- ❑ Phase 1 study completion
- ❑ Advance to Phase 2 POC Study

Investor Relations

T: (650) 900-5470

ir@unicycive.com

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