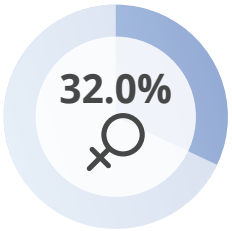
OPTIMIZE (Post-Registrational) | A randomized, open-label study of tenapanor initiation when used as core therapy

333 PATIENTS WITH HYPERPHOSPHATEMIA RECEIVING MAINTENANCE DIALYSIS

Patient characteristics at OPTIMIZE baseline visit



Average age **53 years**

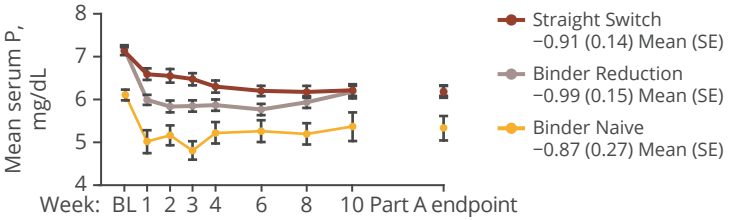
Average time since first dialysis: **54 months**

Patients receiving **hemodialysis and peritoneal dialysis** were included

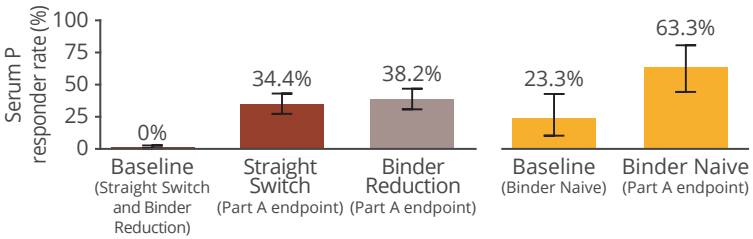
PRIMARY OBJECTIVE

Evaluated tenapanor as core therapy in combination with PBs and as core monotherapy to achieve serum P ≤5.5 mg/dL

Mean Serum P Change From Baseline to Part A Endpoint



Proportion of Patients With Serum P ≤5.5 mg/dL



SAFETY AND TOLERABILITY

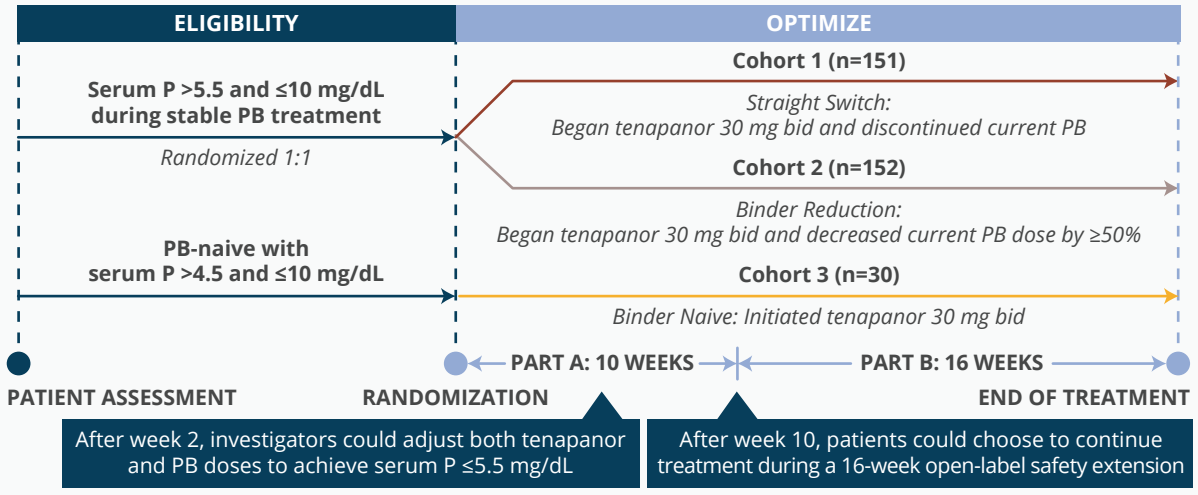
Patients discontinuing tenapanor treatment due to diarrhea through parts A and B (Straight Switch, Binder Reduction, Binder Naive)

11/151 (7.3%) **10/152 (6.6%)** **1/30 (3.3%)**

Any serious event reported through parts A and B (Straight Switch, Binder Reduction, Binder Naive)

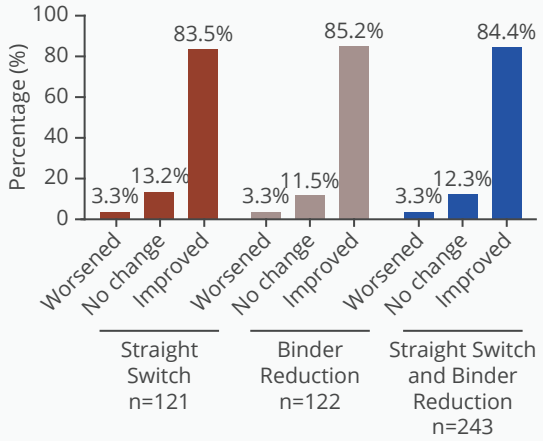
20/151 (13.2%) **26/152 (17.1%)** **4/30 (13.3%)**

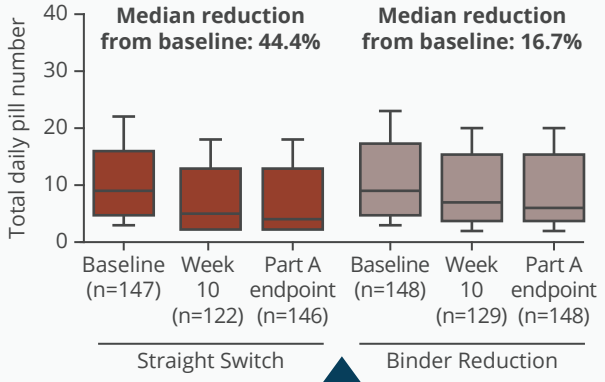
TRIAL DESIGN



OTHER OBJECTIVES FOR PART A: ASSESS PATIENT-REPORTED OUTCOMES AND PHOSPHATE-LOWERING PILL BURDEN

PRO: Feelings About Phosphate Management Routine





The lines inside the boxes indicate the median values. The top and bottom edges of the boxes indicate the IQR from the 25th to 75th percentile. The whiskers extend 1.5 times the IQR

STUDY LIMITATIONS

- No placebo arm
- Endpoints not controlled for type 1 error
- Due to the open-label nature of the study, results are considered descriptive

bid, twice a day; IQR, interquartile range; ISI, important safety information; P, phosphate; PB, phosphate binder; PRO, patient-reported outcome.
NCT04549597. Sprague SM et al. *Kidney360*. 2024;5:732-42.

Please see ISI on the reverse side of this card.

MED-US--2300041 10/2024

INDICATION

XPHOZAH (tenapanor) is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

XPHOZAH is contraindicated in patients under 6 years of age.

XPHOZAH is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

WARNINGS AND PRECAUTIONS

Diarrhea

Patients may experience severe diarrhea. Treatment with XPHOZAH should be discontinued in patients who develop severe diarrhea.

MOST COMMON ADVERSE REACTIONS

Diarrhea, which occurred in 43% to 53% of patients, was the only adverse reaction reported in at least 5% of XPHOZAH-treated patients with CKD on dialysis across trials. The majority of diarrhea events in the XPHOZAH-treated patients were reported to be mild to moderate in severity and resolved over time or with dose reduction. Diarrhea was typically reported soon after initiation but could occur at any time during treatment with XPHOZAH. Severe diarrhea was reported in 5% of XPHOZAH-treated patients in these trials.

Please see full Prescribing Information available at the booth.

CKD, chronic kidney disease.

XPHOZAH (tenapanor hydrochloride). Prescribing information. Ardelyx, Inc; 2023.

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