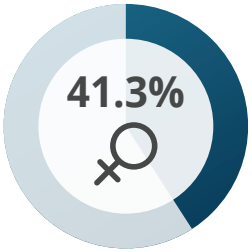
BLOCK (Phase 3) | A 12-week, randomized, placebo-controlled, phase 3 trial of tenapanor for hyperphosphatemia

219 PATIENTS WITH HYPERPHOSPHATEMIA RECEIVING MAINTENANCE DIALYSIS

Baseline characteristics during the RTP



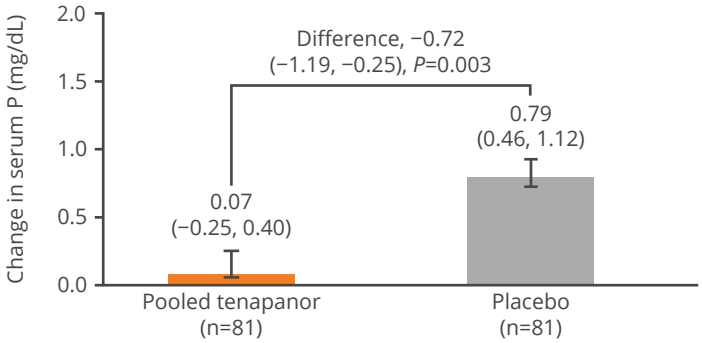
Average age **56 years**

Average time since first dialysis: **59 months**

Patients receiving **hemodialysis** were included

PRIMARY ENDPOINT

Change in serum P from the end of the RTP to the end of the RWP (or the end point visit for this period) for the pooled tenapanor and placebo groups



SAFETY AND TOLERABILITY

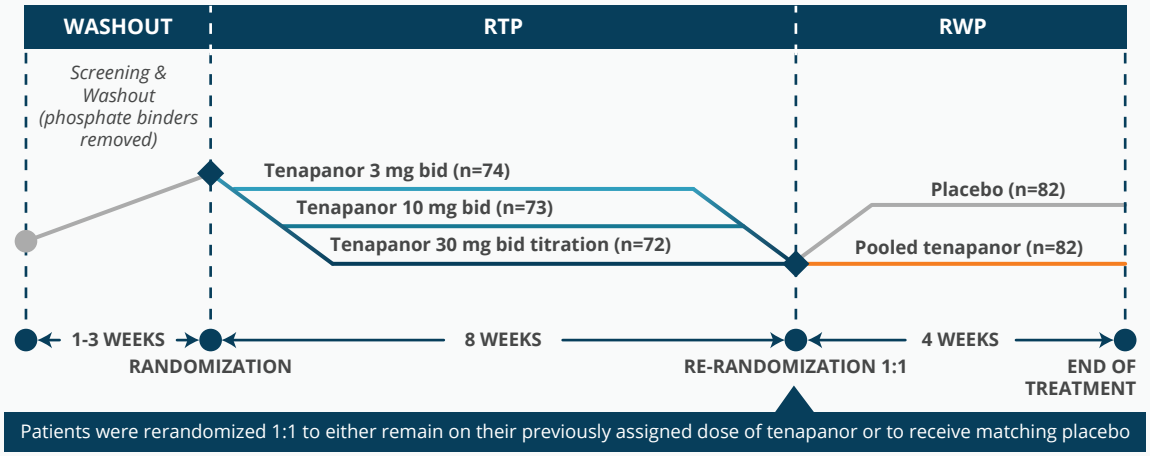
Patients reporting diarrhea during the RTP

Tenapanor 3 mg bid	Tenapanor 10 mg bid	Tenapanor 30 mg bid
22/74 (29.7%)	30/73 (41.1%)	34/71 (47.9%)

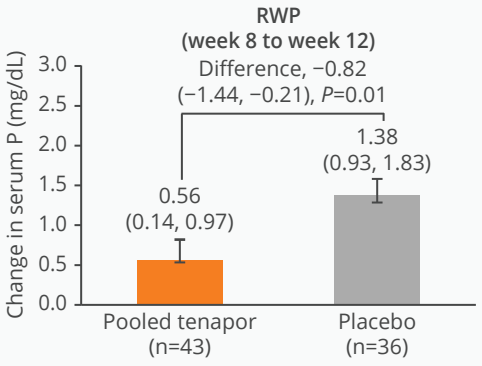
Any serious event reported during the RTP

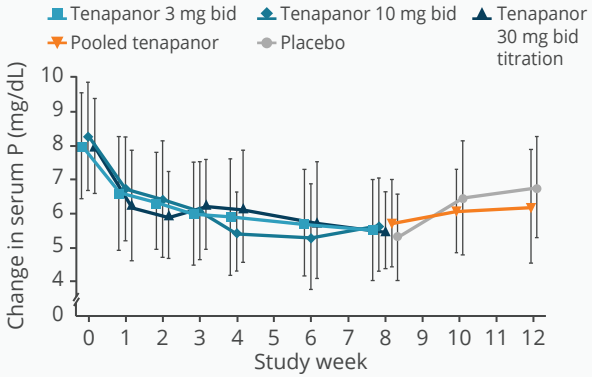
Tenapanor 3 mg bid	Tenapanor 10 mg bid	Tenapanor 30 mg bid
11/74 (14.9%)	5/73 (6.8%)	5/71 (7.0%)

TRIAL DESIGN



SECONDARY ANALYSIS: CHANGE IN SERUM P FROM THE END OF THE RTP TO THE END OF THE RWP AMONG RESPONDERS[a]





[a]A responder analysis was requested by the FDA and therefore this analysis was performed using the efficacy analysis population, defined as patients who experienced at least a 1.2-mg/dL decrease in serum phosphate during the RTP.

STUDY LIMITATIONS

- The protocol was modified after the trial was launched (at the request of the FDA), changing the primary outcome
- Conclusions drawn from the responder analysis have limited generalizability
- These results should be interpreted with caution as this part of the trial was open label with no placebo control

bid, twice a day; FDA, Food and Drug Administration; ISI, important safety information; P, phosphate; qd, once a day; RTP, randomized treatment period; RWP, randomized withdrawal period.
NCT02675998. Block GA et al. *J Am Soc Nephrol*. 2019;30:641-52.

Please see ISI on the reverse side of this card.
MED-US--2300050 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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