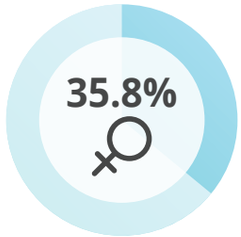
Phase 2b | A 6-week, randomized, placebo-controlled, multicenter trial of tenapanor for hyperphosphatemia

162 PATIENTS WITH HYPERPHOSPHATEMIA RECEIVING MAINTENANCE DIALYSIS

Patient characteristics at baseline visit

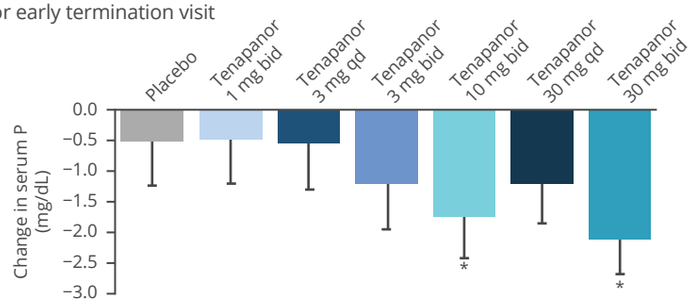


Average age
59 years

Patients receiving
hemodialysis were included

PRIMARY ENDPOINT

Change in serum P concentration from baseline to the end of treatment or early termination visit



	Placebo	Tenapanor 1 mg bid	Tenapanor 3 mg qd	Tenapanor 3 mg bid	Tenapanor 10 mg bid	Tenapanor 30 mg qd	Tenapanor 30 mg bid
Baseline[a]	7.87±1.49	7.55±1.00	7.73±1.28	7.32±1.01	7.92±1.06	7.61±0.85	7.76±1.18
Change from baseline at EOT/ET[b]	−0.54 (−1.21, 0.13)	−0.47 (−1.18, 0.24)	−0.56 (−1.28, 0.17)	−1.18 (−1.93, −0.44)	−1.70 (−2.41, −0.99)	−1.11 (−1.85, −0.37)	−1.98 (−2.67, −1.28)
n (baseline, EOT/ET)	26, 26	23, 23	22, 22	21, 21	23, 23	21, 21	25, 24

*P<0.05 vs placebo. [a]Mean±SD. [b]Least squares mean (95% CI): P=0.01.

SAFETY AND TOLERABILITY

Patients reporting diarrhea during the RTP
(**pooled tenapanor** vs **placebo**)

55/135 (40.7%)

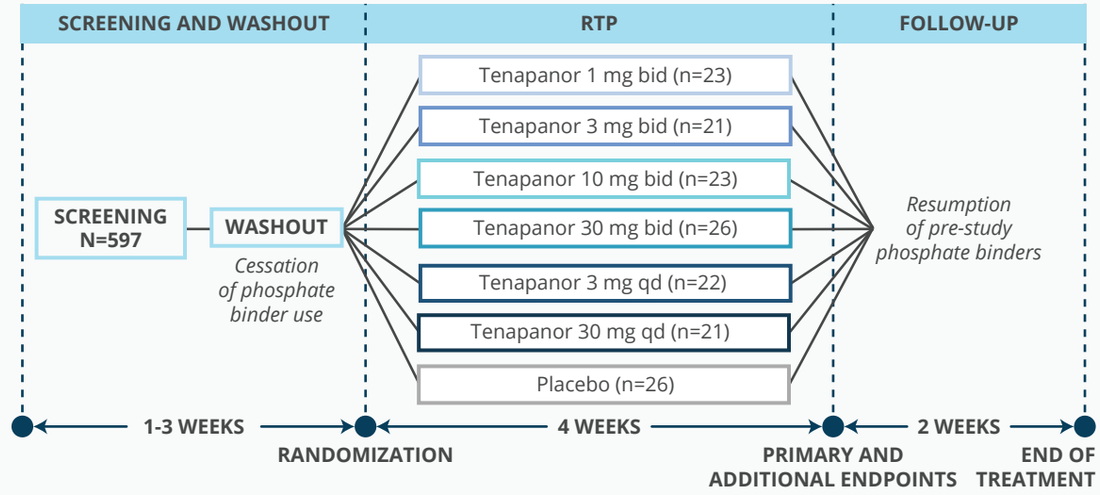
3/26 (11.5%)

Any serious event reported during the RTP
(**pooled tenapanor** vs **placebo**)

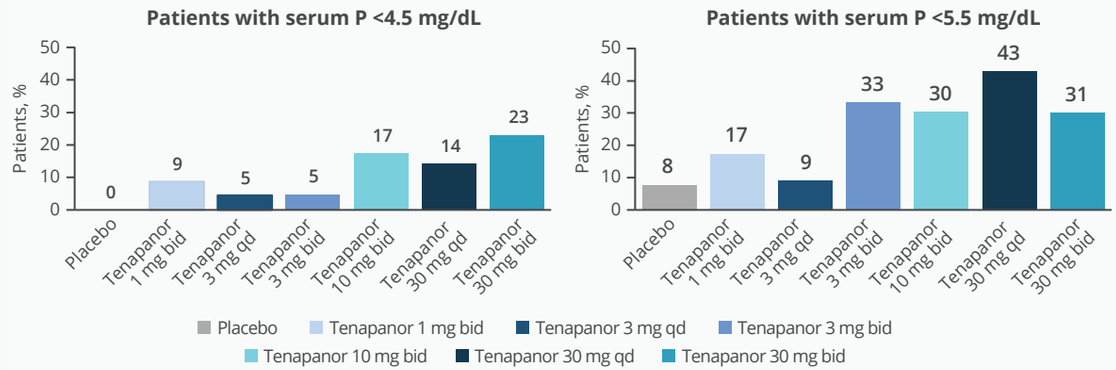
10/135 (7.4%)

4/26 (15.4%)

TRIAL DESIGN



ADDITIONAL ENDPOINTS: PROPORTION OF PATIENTS ACHIEVING SERUM P <4.5 mg/dL AND <5.5 mg/dL AT END OF TREATMENT OR EARLY TERMINATION VISIT



STUDY LIMITATIONS

- Short duration
- Fixed treatment dose with no dose titration
- Modest number of patients per group with some slight imbalances in demographic characteristics

bid, twice a day; EOT, end of treatment; ET, early termination; ISI, important safety information; P, phosphate; qd, once a day; RTP, randomized treatment period.
NCT02081534. Block GA et al. *J Am Soc Nephrol*. 2017;28:1933-42.

Please see ISI on the reverse side of this card.
MED-US--2300053 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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