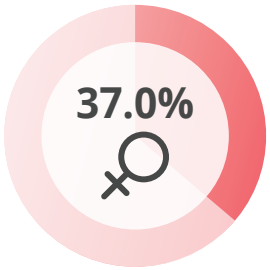
NORMALIZE (Post-Registrational) | An 18-month extension of the one-year PHREEDOM trial of tenapanor

172 PATIENTS HAVING COMPLETED THE PHREEDOM STUDY

Patient characteristics at NORMALIZE baseline visit



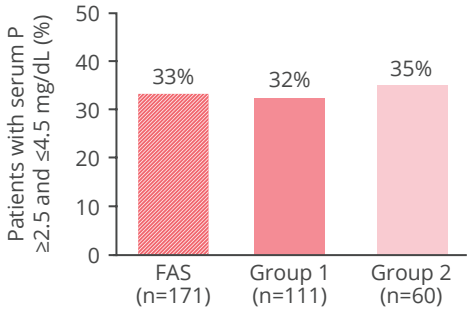
Average age **57 years**

Average time since first dialysis: **65 months**

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

PRIMARY ENDPOINT

Proportion of patients achieving serum P within the population reference range (2.5-4.5 mg/dL) at the end-of-study visit



The mean (SE) reduction in serum P was 2.0 (0.2) mg/dL from PHREEDOM baseline to the NORMALIZE end-of-study visit.

SAFETY AND TOLERABILITY

Patients reporting diarrhea (Group 1 vs Group 2):

11/111 (10%)

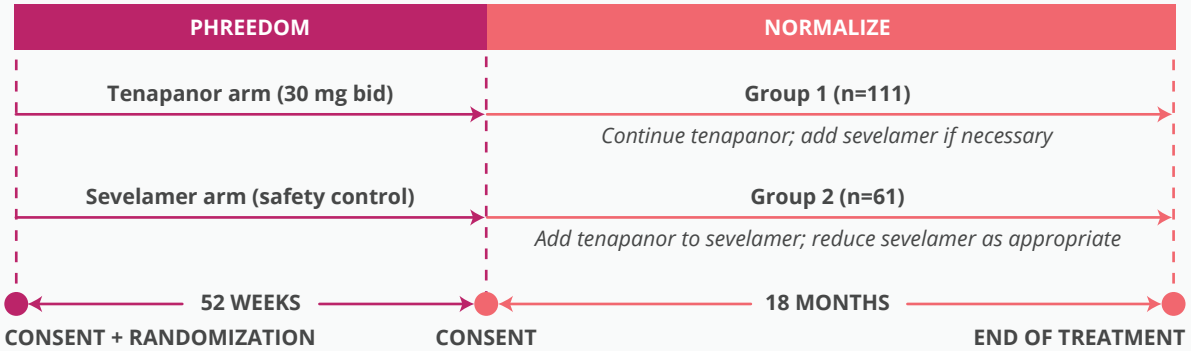
27/60 (44%)

Any serious event reported (Group 1 vs Group 2):

56/111 (50%)

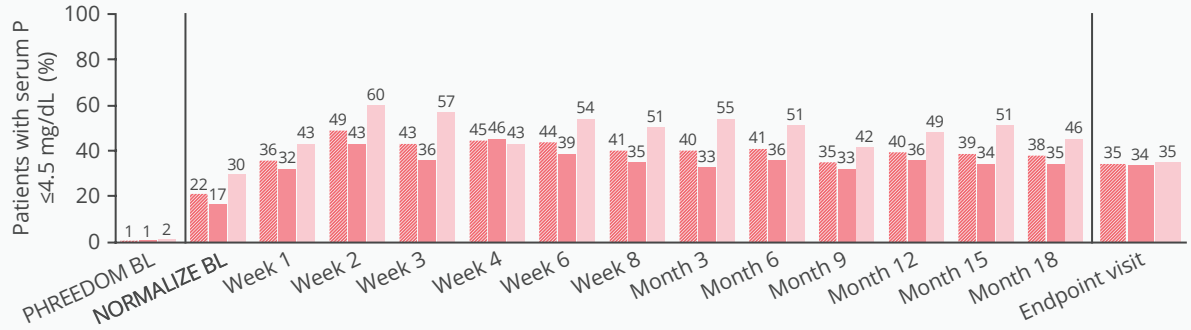
22/60 (36%)

TRIAL DESIGN

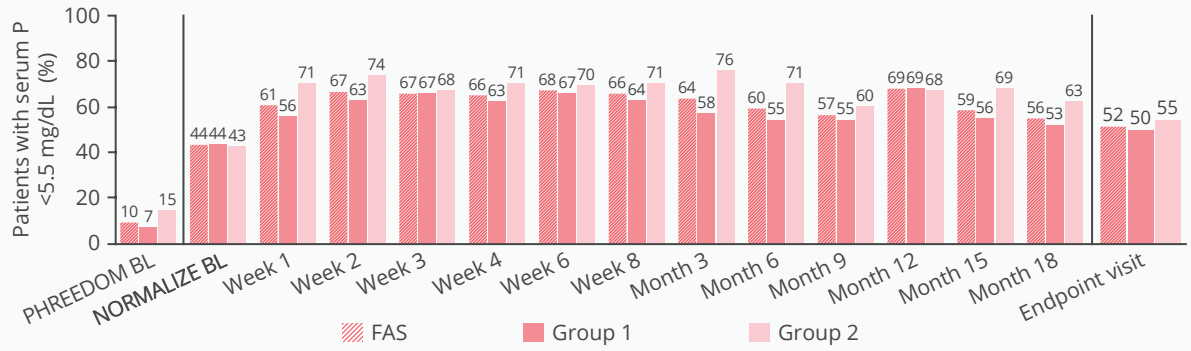


SECONDARY ENDPOINT: PROPORTION OF PATIENTS ACHIEVING SERUM P ≤4.5 mg/dL AND <5.5 mg/dL AT EACH POSTBASELINE VISIT

Patients With Serum P ≤4.5 mg/dL



Patients With Serum P <5.5 mg/dL



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bid, twice a day; BL, baseline; FAS, full analysis set; ISI, important safety information; P, phosphate.
NCT03427125. Silva A et al. *Kidney360*. 2023;4:1580-89.

Please see ISI on the reverse side of this card.

MED-US--2300034 10/202

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.

MED-US--2300034 10/2024