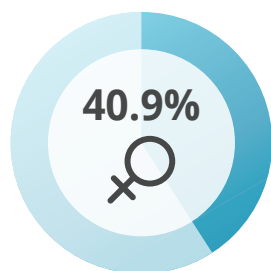


236 PATIENTS UNDERGOING MAINTENANCE DIALYSIS WITH HYPERPHOSPHATEMIA (SERUM P 5.5–10 mg/dL) DESPITE RECEIVING PHOSPHATE BINDER THERAPY.....

Patient characteristics at AMPLIFY baseline visit



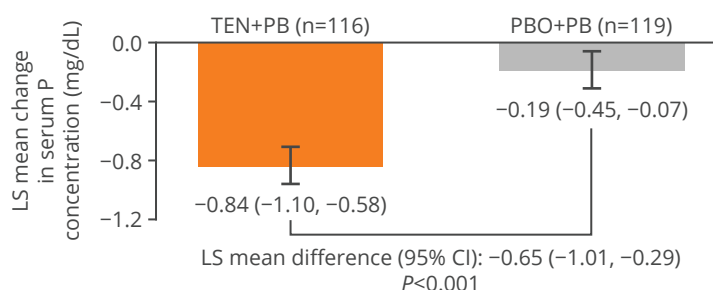
Average age
55 years

Average time since first dialysis: **51 months**

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

PRIMARY ENDPOINT.....

Change in serum P concentration from baseline to week 4 in TEN+PB compared with PB+PBO.



SAFETY AND TOLERABILITY.....

Diarrhea was the most common adverse event. Patients reporting diarrhea (TEN+PB vs PBO+PB):

50/117 (43%)



8/119 (7%)



Any serious event (TEN+PB vs PBO+PB):

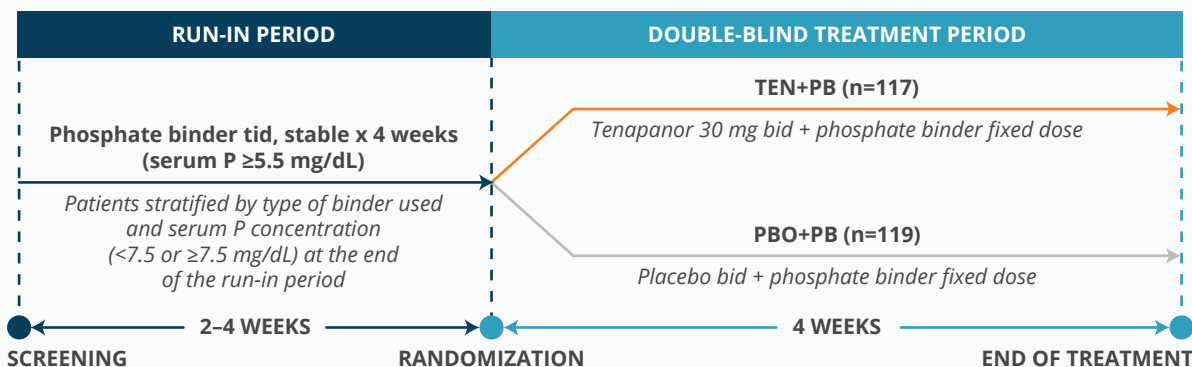
3/117 (3%)



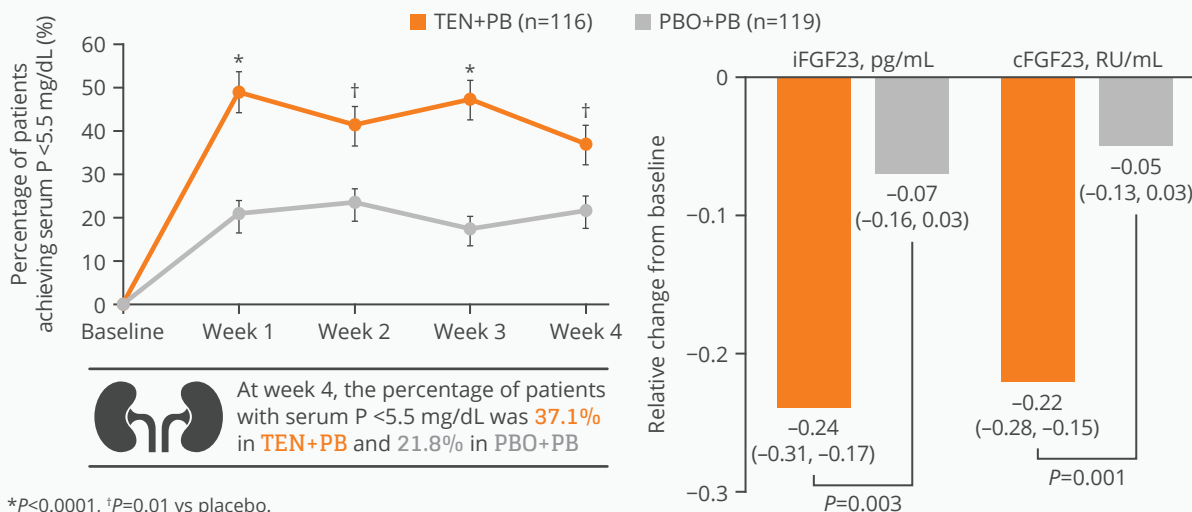
5/119 (4%)



TRIAL DESIGN



SECONDARY ENDPOINTS: PROPORTION OF PATIENTS ACHIEVING SERUM P <5.5 mg/dL, AND RELATIVE CHANGE FROM BASELINE IN iFGF23 AND cFGF23 CONCENTRATIONS, AT WEEK 4



STUDY LIMITATIONS

- Short-term duration
- For patients who did not achieve serum P <5.5 mg/dL with tenapanor and binder, additional time to optimize doses may be beneficial

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.