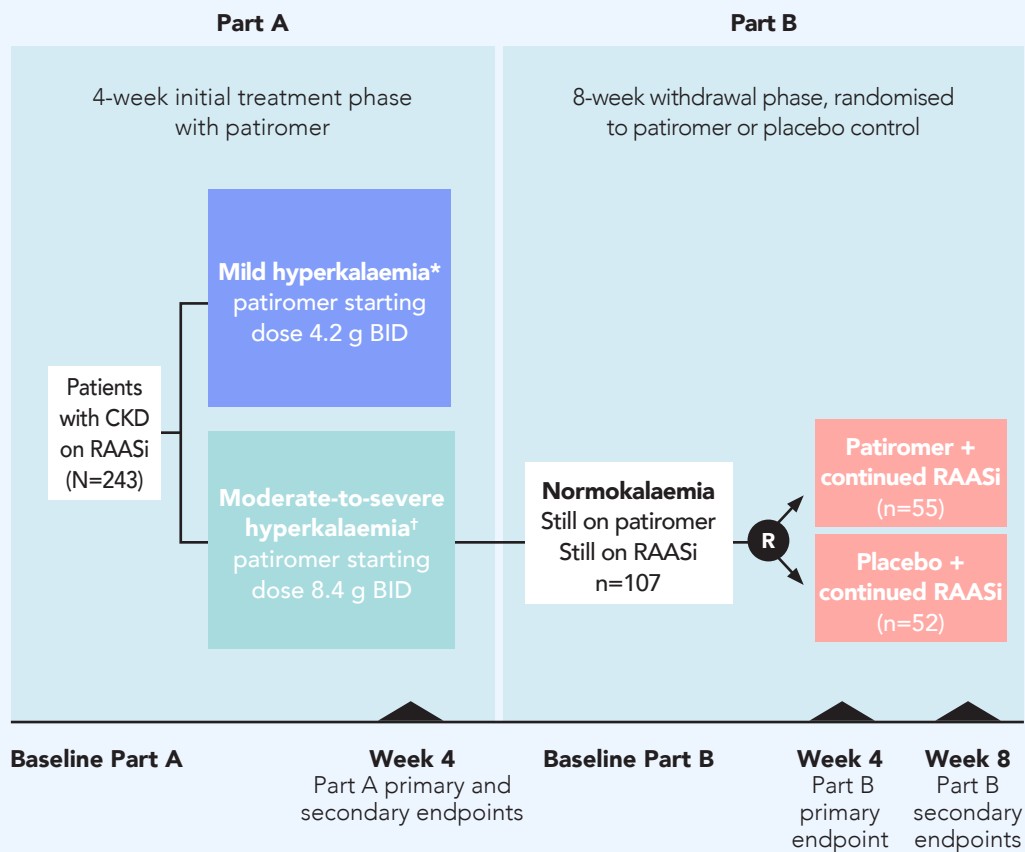


OPAL-HK STUDY

Efficacy and safety of patiromer for the treatment of hyperkalaemia in patients with CKD receiving RAASi¹

STUDY DESIGN

Inclusion criteria: patients with stage 3–4 CKD (eGFR <60mL/min/m²) with hyperkalaemia (sK⁺ 5.1 to <6.5 mEq/L) using RAASi



Comorbidities/treatments at baseline: CKD (100%), HF (42%), T2DM (57%), hypertension (97%), RAASi (100%)

*Mild hyperkalaemia defined as baseline sK⁺ 5.1 to <5.5 mEq/L; †Moderate-to-severe hyperkalaemia defined as baseline sK⁺ 5.5 to <6.5 mEq/L

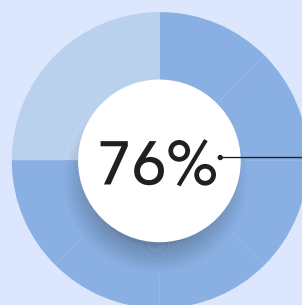
RESULTS

4-week initial treatment phase outcomes

Primary endpoint:

↓
Patiromer treatment significantly reduced elevated sK⁺ levels

–1.01 mEq/L mean change from baseline to Week 4



Secondary endpoint:

76% of patients treated with patiromer had sK⁺ in target range at Week 4

OPAL-HK STUDY

RESULTS

8-week randomised withdrawal phase outcomes



Patiomer maintained **normal sK⁺ levels**



sK⁺ levels increased with placebo
(between-group difference of 0.72 mEq/L)

Reduced RAASi dose due to hyperkalaemia*

Patiomer (**6%**)
Placebo (**66%**)

*At least one sK⁺ level ≥ 5.5 mmol/L

Discontinued RAASi due to hyperkalaemia

Patiomer (**6%**)
Placebo (**56%**)

Patients on RAASi

Patiomer (**94%**)
Placebo (**44%**)

Safety



Most common adverse event: mild-to-moderate constipation (11% during initial treatment; 4% during randomised withdrawal phase)

This generally **did not** limit treatment with patiomer



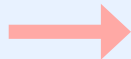
The rates of all other adverse events with patiomer were low and similar to those with placebo in the randomised withdrawal phase

CONCLUSIONS

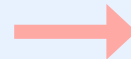
OPAL-HK demonstrated that patiomer...



...provides significant and clinically meaningful sK⁺ reduction



...maintains normal K⁺ levels



...and has the ability to keep patients on RAASi medications



Recurrence of hyperkalaemia upon treatment withdrawal demonstrates the need for long-term treatment

Abbreviations: BID, twice a day; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; HF, heart failure; RAASi, renin-angiotensin-aldosterone system inhibitors; sK⁺, serum K⁺; T2DM, type 2 diabetes mellitus.

1. Weir MR et al. Patiomer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors. *N Engl J Med* 2015;372:211-21.