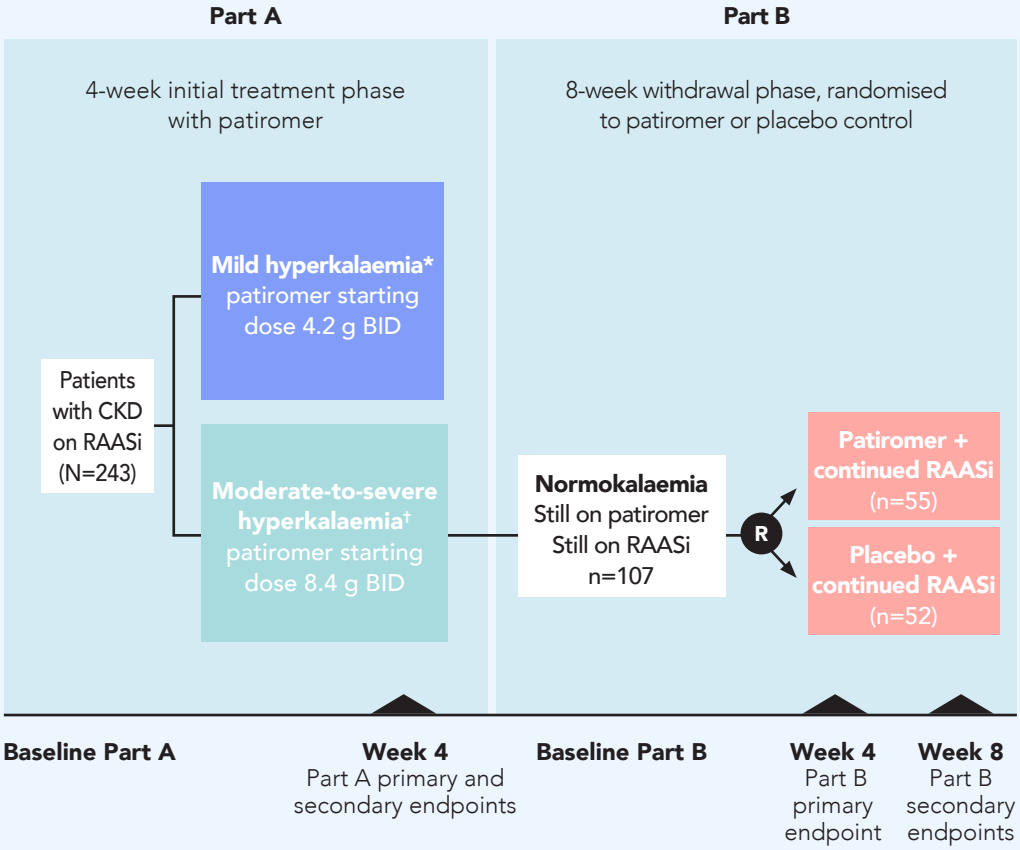
OPAL-HK STUDY

Efficacy and safety of patiromer for the treatment of hyperkalaemia in patients with CKD receiving RAASi[1]

STUDY DESIGN

Inclusion criteria: patients with stage 3–4 CKD (eGFR <60mL/min/m^2) 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

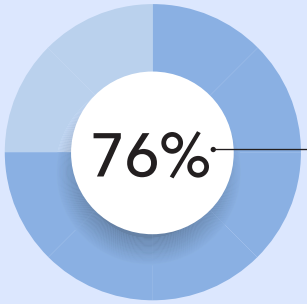
RESULTS

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

Patiromer maintained **normal sK⁺ levels**

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

Reduced RAASi dose due to hyperkalaemia*

Patiromer (**6%**)
Placebo (**66%**)

*At least one sK+ level ≥5.5 mmol/L

Discontinued RAASi due to hyperkalaemia

Patiromer (**6%**)
Placebo (**56%**)

Patients on RAASi

Patiromer (**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 patiromer

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

CONCLUSIONS

OPAL-HK demonstrated that patiromer...

...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.* Patiromer in patients with kidney disease and hyperkalemia receiving RAAS inhibitors. *N Engl J Med* 2015;372:211–21.

VIFOR PHARMA

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