[EDITABLE STUDY CENTRE ADDRESS]
[EDITABLE STUDY CENTRE ADDRESS]
[EDITABLE STUDY CENTRE ADDRESS]

[EDITABLE DATE]

Introducing the 1378-0023 (EASi-SYNC™) clinical study for patients with chronic kidney disease at risk of progression

Dear [EDITABLE HCP NAME],

The 1378-0023 (EASi-SYNC™) study is a Phase II clinical study assessing vicadrostat, an investigational aldosterone synthase inhibitor, in combination with empagliflozin, a well-established sodium-glucose co-transporter 2 (SGLT2) inhibitor for the treatment of chronic kidney disease (CKD).

Preliminary clinical data suggest that this combination may provide additive kidney protection and simultaneously reduce the risk of hyperkalaemia.[1] To build on these findings, our site is participating in the EASi-SYNC™ study to determine whether simultaneous versus staggered initiation of vicadrostat and empagliflozin offers the greatest therapeutic benefit for patients with CKD.

We are looking for approximately 400 adults to join this study who, in addition to other criteria, have:

- Evidence of CKD at risk of progression, documented by two estimated glomerular filtration rate (eGFR) measurements taken within the past year, with each measurement ≥20 and <60 mL/min/1.73m^2, irrespective of urine albumin creatinine ratio (UACR)
- Received treatment with a stable dose of either an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB) (but not both together) for at least 4 weeks prior to study enrolment
- **Not** received an SGLT2 inhibitor within the 4 weeks prior to study enrolment*

*Please note, SGLT2 inhibitor treatment should not be interrupted just to enrol patients in this study.

Patients who enrol in the EASi-SYNC™ study will take part for 16 weeks, including 2 weeks for screening, 12 weeks for treatment, and 2 weeks for follow-up. During this time, they will be randomised 1:1 to receive either simultaneous initiation of vicadrostat and empagliflozin for 12 weeks, or staggered initiation of placebo-matching vicadrostat and empagliflozin for 6 weeks, followed by vicadrostat and empagliflozin for 6 weeks.

If you know of any patients who may qualify, or would like more information, please contact us using the details below. We will be happy to answer any questions you have.

[EDITABLE NAME]

Part of the EASi-SYNC™ study team

[INSERT CONTACT DETAILS]

References

1. Randomised, double-blind, placebo-controlled and parallel dose group trial to investigate efficacy and safety of multiple doses of oral BI 690517 over 14 weeks, alone and in combination with empagliflozin, in patients with diabetic and non-diabetic chronic kidney disease. Clinical trial report 1378-0005. 2024.