Study Treatment Information Leaflet

This leaflet contains important information relating to your EMPA-KIDNEY study treatment. Please read all the information contained in this leaflet very carefully. If you have any questions about your study treatment, please speak to your local study nurse or feel free to call an UK EMPA-KIDNEY study nurse or doctor on: **Freefone 0808 164 4060**

Please keep this information leaflet in a safe place for future reference.

Throughout the study you will be provided with one type of study treatment:

- Pills/tablets of **empagliflozin 10 mg** or **matching placebo (inactive)**

Initial Run-in phase

After your first study visit (the Screening Visit) you will enter the "Run-in phase". You will be issued with a pack of **Type F Run-in Treatment** containing 3 wallets of study treatment, each wallet containing 35 pills.

Long-term phase

At your second scheduled study visit (the Randomization Visit), if you proceed into the long-term part of the study, you will be randomly allocated to receive pills containing either empagliflozin 10 mg or matching placebo.

At the Randomization Visit, and at every 6-monthly Follow-up Visit thereafter, you will be issued with **two** packs of **Type R Randomized Treatment** each pack containing 3 wallets of study treatment, with each treatment wallet containing 35 pills/tablets.

Opening the Treatment Wallets

To open a treatment wallet you need to press with your thumb on the left hand side (where marked) and pull the wallet from its sleeve from the right hand side.

***** Please retain and bring all your used and unused study treatment wallets to each study appointment *****

EMPA-KIDNEY

MRC Population Health Research Unit | UNIVERSITY OF OXFORD

About your EMPA-KIDNEY study pills

Empagliflozin 10 mg or matching placebo

- Oral use only
- No special storage conditions
- Keep out of the reach of children
- For clinical trial use only

- Unless otherwise instructed, you should take ONE pill by mouth each day at about the same time (with or without food)
- Although the pills in the treatment wallets are numbered 1 to 28, with an additional 7 pills shaded in grey, it does not matter which one you start with. You should aim to take each of the 35 tablets in a wallet before starting a new treatment wallet
- If you forget to take a pill at your usual time, you may still take it later the same day. However, if you miss a whole day or more, do not make up for the missed pills on the day you restart
- If you think you will reach the end of your pills before your next clinic visit or if you lose your pills, please contact your local study nurse or call the EMPA-KIDNEY office and we will arrange for replacement pills to be provided
- Please retain all used and unused treatment wallets and bring them to your next clinic visit
- Study treatment should generally be temporarily stopped on days that you are unable to eat, such as during an illness or in preparation for medical procedures. For scheduled major operations, you may be advised to stop treatment for 3 days before surgery. Study treatment should be restarted on discharge, unless you are instructed otherwise by your doctor
- For women: if you become pregnant or plan to get pregnant while taking the study pills please stop them immediately and inform your local study nurse or call **Freefone 0808 164 4060** as soon as possible

Possible side effects

If you have diabetes, you may be at risk of ketoacidosis. This is particularly the case if you have type 1 diabetes. Participants with diabetes will be provided with an additional patient information leaflet about this.

The study pills might increase the chance of a urine or genital tract infection, like thrush. These infections are usually easily treated with a course of antibiotics or antifungal pills. If such treatment is ever needed, your GP or local study team could help diagnose and treat you. You can also contact the EMPA-KIDNEY office and we can arrange for the local study team to help you.

The study pills may lower your blood pressure. If you feel light-headed or dizzy on standing, please inform your local study nurse or the EMPA-KIDNEY office. We can arrange for you to see your local study nurse in the next few days for a review where necessary.

Further information about side effects of empagliflozin is given in the **EMPA-KIDNEY Participant Information Leaflet**. If any new important information arises during the course of the study staff will discuss this with you. Updated information will also be available on the study website (**www.empakidney.org**).

If you develop any symptoms that you think are related to your study medication, please contact your **local study nurse** or call **Freefone 0808 164 4060** for further advice.

Other medications

Empagliflozin is a sodium-glucose co-transporter-2 inhibitor. This class of drug can be recognized by the following letters at the end of the name "gliflozin". Examples include empagliflozin, dapagliflozin, and canagliflozin. If your local doctor thinks you should definitely start such a drug, you should stop your study treatment first.

You or they may call **Freefone 0808 164 4060** with any queries.

Study treatment delivery

You will normally receive study treatment at face-to-face study clinic visits. It may be necessary during the trial to conduct your follow-up appointments by telephone (as was the case during the Covid-19 pandemic). It may be possible to deliver study treatment to you by courier in this (or a similar) situation. If this is required the research team will contact you to seek your verbal permission and explain further details.

EMPA-KIDNEY UK Coordinating Office,
Clinical Trial Service Unit (CTSU)
Richard Doll Building, University of Oxford
Roosevelt Drive, OXFORD, OX3 7LF

Tel: **0808 164 4060 (Freefone)** or +44 (0)1865 743868 (from outside UK)
Email: cco.empakidney@ndph.ox.ac.uk Website: www.empakidney.org