

Dear Colleagues,

Thank you for taking the time to read this broadcast. We are looking for potential participants for the BaxDuo-Pacific Study in South Africa.

Study overview

BaxDuo-Pacific is a phase 3 study evaluating the efficacy and safety of baxdrostat in combination with dapagliflozin vs dapagliflozin in people with CKD and hypertension. The study aims to evaluate whether baxdrostat and dapagliflozin can reduce the risk of sustained decline in eGFR, kidney failure, HF events or CV death more effectively than dapagliflozin alone.

Study treatments

- Baxdrostat is a highly selective aldosterone synthase inhibitor that can significantly reduce aldosterone levels, offering the potential to not only improve BP in CKD patients, but also ameliorate the negative impacts of aldosterone on kidney function. The drug is already approved in USA and UAE for the treatment of hypertension. High aldosterone levels observed in patients with CKD have been associated with eGFR decline and end-stage kidney disease
- Dapagliflozin is an SGLT2 inhibitor, approved in many countries, which has demonstrated cardiorenal benefits in CKD patients with and without diabetes

It is thought that, together, baxdrostat and dapagliflozin may provide additive benefits by targeting complementary blood pressure-dependent and -independent pathways.

Key Eligibility Criteria:

- ≥ 18 years old.
- eGFR 30-59 mL/min/1.73 m²
- UACR ≥ 500 mg/g (56.5 mg/mmol) and ≤ 5000 mg/g (565 mg/mmol)
- History of HTN and a SBP ≥ 130 mmHg
- Stable and maximum tolerated dose of an ACEi or an ARB (not both)
- Serum or plasma potassium ≥ 3.0 and ≤ 4.8 mmol/L if eGFR ≥ 45 mL/min/1.73 m²
- Or Serum or plasma potassium ≥ 3.0 and ≤ 4.5 mmol/L if eGFR < 45 mL/min/1.73 m²

We will assess further inclusion and exclusion criteria at the screening visit to determine eligibility.

The **main focus** is on identifying patients with the following:

- eGFR 30-59 mL/min/1.73 m²
- UACR ≥ 500 mg/g (56.5 mg/mmol) and ≤ 5000 mg/g (565 mg/mmol)

Participating Sites:

We would appreciate it if you could refer any potential participants to one of the participating sites mentioned below:

Site	PI	Location	Contact Details
Groote Schuur Hospital	Prof B Rayner	Cape Town	⇒ brian.rayner@uct.ac.za
Langeberg Clinical Trials	Dr J Trokis	Cape Town	⇒ 083 774 4588 ⇒ Cassandra.langeberg@gmail.com
Midrand Medical Centre	Dr A Jacovides	Midrand, Johannesburg	⇒ 082 449 8354
Diabetes Care Centre & CDE Centre	Dr M Joshi	Benoni	⇒ 011 8941491 / 076 920 0383 (Mariam) ⇒ dccjosh@telkomsa.net
Dr. G.H. Latiff, Lenmed Shifa Private Hospital	Dr G Latiff	Sydenham, Durban	⇒ 0837864661 ⇒ drlatiff@iafrica.com
Dr Makan Centre of Diabetes	Dr H Makan	Lenasia	⇒ 083 799 8056 ⇒ h.makan@megaweb.co.za
Newtown Clinical Research Centre	Dr E Mitha	Newtown, Johannesburg	⇒ 082 322 3402 ⇒ emitha@newtowncrc.co.za
Dr D Pillay Private Practice	Dr D Pillay	Stanger Manor, KwaDukuza	⇒ 032 551 2679 ⇒ deenp@iafrica.com
InnoMed Clinical Trial Centre	Dr MMDV Basson	Bellville	⇒ 0823252672
Bloemfontein Medi-Clinic	Dr D Khutsoane	Bloemfontein	⇒ 0834400145 ⇒ d@khut.bfnmcc.co.za
Dr N Moosa	Dr N Moosa	Lenasia	⇒ 082 338 6688 ⇒ naeem@drnmoosa.co.za

Thank you for taking the time to consider the BaxDuo-Pacific study for your patients. We hope to establish a valuable partnership with you as we endeavour to find the right patients for this study.

Sincerely,

Pranitha Chetty on behalf of the Bax-Duo-Pacific Team, South Africa