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Promoting Sustainable Kidney Health: The Asia-Pacific and Beyond

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Can Autologous Cell Treatment Preserve Kidney Function and Delay Progression of Advanced Chronic Kidney Disease?

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Despite recent advances in available therapies for CKD and T2DM, including SGLT2i and GLP-1 medications, many patients continue to progress to ESKD. Novel cell-based therapies may preserve kidney function and delay dialysis by reparative and anti-inflammatory mechanisms. ProKidney has introduced an autologous cell-based therapy, rilparencel, into clinical research. In a phase 2 study, eighty-three participants with T2DM and CKD with an eGFR between 20-50 ml/min/1.73 m^2 and A1c< 10% were enrolled. After a percutaneous kidney biopsy and ex-vivo culture expansion of selected renal cells, patients were randomized into two groups: G1 (active treatment) received up to two injections of rilparencel or G2 (deferred treatment), treatment with rilparencel was delayed for 12 months. Both groups received standard of care (SoC) and followed up to 24 months after the last injection. Injections were administered into the cortex of the same kidney that was biopsied under CT guidance. The primary efficacy and safety endpoints were change in eGFR and procedure- and product-related adverse events (AEs). The characteristics at screening were similar in both groups: eGFR (mean +/-SD) in G1 (n=39) 32.8 +/-8.5 ml/min/1.73 m^2 and in G2 (n=42), 32.0+/- 8.1. 12 months after baseline eGFR decreased by 3.7, 4.7, and 1.1 ml/min/1.73 m^2 in G1, G2 (SoC to 12 months) and G2 (after rilparencel injection), respectively. The procedure AEs were as expected in this population. In this RCT, some participants with T2DM and advanced CKD experienced less decline in eGFR after receiving rilparencel compared to only SoC. Kidney function stabilized in a subgroup of patients with stage 4 CKD and severe albuminuria (Figure). Procedure and product AEs were tolerable and consistent with expected events from percutaneous renal interventions. It is our hypothesis that this novel cell-based therapy could represent an alternative for patients who are at high risk of kidney disease progression.

Keywords: chronic kidney disease progression, diabetic nephropathy, cell therapy, randomized clinical trial

ProKidney Results_.jpg