

Publication of a clinical phase 2 study: SCO-792, an enteropeptidase inhibitor, is safe and well-tolerated and may be associated with decreased UACR in patients with T2DM and albuminuria

Kanagawa, Japan, October 14, 2022 – In a new study published by *Kidney International Reports*, a research and development team at SCOHIA PHARMA, Inc., reported the results from an exploratory phase 2 clinical trial for SCO-792, an orally bioavailable enteropeptidase inhibitor.

<u>Article title</u> An exploratory randomized trial of SCO-792, an enteropeptidase inhibitor, in patients with type 2 diabetes and albuminuria https://doi.org/10.1016/j.ekir.2022.10.006

Elevated plasma amino acid levels overload kidney function through increased glomerular filtration rate (GFR). Blocking gut amino acid intake may have therapeutic benefits for patients with kidney dysfunction.

In a prospective phase 2 clinical trial, our team conducted an exploratory evaluation of the safety and efficacy of SCO-792, an enteropeptidase inhibitor that blocks gut amino acid intake. This study was conducted in patients with type 2 diabetes mellitus (T2DM) and albuminuria, who had received renin-angiotensin system inhibitors and anti-hyperglycemic agents. Seventy-two patients with T2DM were included in this study, with a urine albumin-creatinine ratio (UACR) of 200–5,000 mg/g and an estimated GFR > 30 mL/min/1.73 m². Patients were randomly assigned into the three groups (1:2:2), namely placebo (n = 15), SCO-792 500 mg once daily (SCO-792 QD; n = 29), or SCO-792 500 mg thrice daily (SCO-792 TID; n =28) and received treatment for 12 weeks. Primary endpoints were defined as safety, tolerability, and UACR changes from the baseline.

Results showed that SCO-792 was safe and well tolerated up to 1,500 mg/day for 12 weeks. These observations were accompanied by UACR changes from baseline of -14% (*P*=0.4407), -27% (*P*=0.0271), and -28% (*P*=0.0211) in placebo, SCO-792 QD, and SCO-792 TID, respectively.

With our phase 2 trial, it is suggested that SCO-792 may promote decreased UACR from baseline in patients with T2DM and albuminuria, making this a potential therapeutic drug for kidney disease. Nonetheless, further clinical studies are essential to confirm our findings.

SCOHIA is actively seeking a partner worldwide for further development and commercialization of SCO-792.



About SCOHIA PHARMA, Inc.:

SCOHIA PHARMA, Inc. is a drug discovery company focusing on the field of lifestyle-related diseases such as cardiovascular, metabolic, and renal diseases where high unmet medical needs still remain. Our R&D team has a rich pipeline and track record in each stage of drug development, including compound discovery, drug evaluation, and clinical development, which makes us special. For detailed information about SCOHIA PHARMA, Inc., please visit https://www.scohia.com/eng/.

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