



Publication of a clinical phase 1 study: SCO-267, a GPR40 full agonist, is safe and well-tolerated, exhibits good potential for once-daily dosing, and improves glycemic control in humans

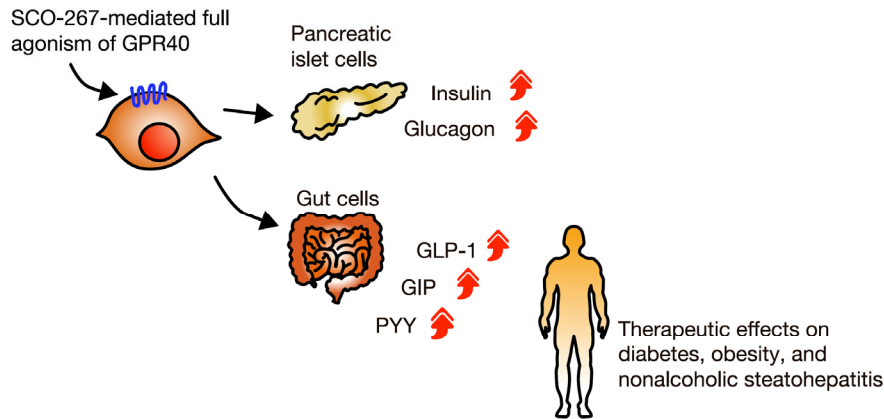
Kanagawa, Japan, July 29, 2021 – In a new study published by *Diabetes*, a research and development team at SCOHIA PHARMA, Inc., reported the results of a phase 1 clinical trial for SCO-267, an orally bioavailable GPR40 full agonist.

Article title

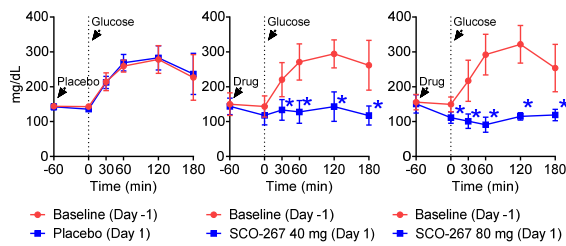
SCO-267, a GPR40 Full Agonist, Stimulates Islet and Gut Hormone Secretion and Improves Glycemic Control in Humans

<https://diabetes.diabetesjournals.org/lookup/doi/10.2337/db21-0451>

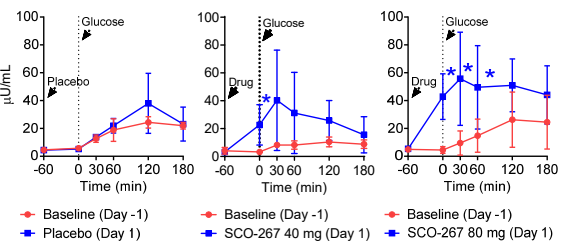
Free fatty acid receptor 1 (GPR40) physiologically regulates the hormonal secretion of pancreatic islet and enteroendocrine cells; SCO-267 is potentially a first-in-class full agonist of this receptor¹⁻⁴. The current study reported that SCO-267 was safe and well tolerated at all tested doses, and exhibited good potential for once-daily dosing in humans. Moreover, SCO-267-mediated full agonism of GPR40 was demonstrated to stimulate secretion of both islet and gut hormones, including insulin, glucagon, glucagon-like peptide 1, glucose-dependent insulinotropic polypeptide, and peptide YY, in humans⁵. Oral administration of SCO-267 remarkably decreased fasting hyperglycemia and improved glycemic control during an oral glucose tolerance test in diabetic patients, without inducing hypoglycemia. These results collectively suggest a clinical potential of SCO-267 in treating diabetes. Based on its ability to stimulate islet and gut hormones, which regulate metabolism and body weight, SCO-267 may exhibit clinical benefits in treating diabetes, obesity, and nonalcoholic steatohepatitis. Therefore, SCO-267 is currently being prepared for a phase 2 clinical trial. SCOHIA is actively seeking a partner worldwide for further development and commercialization of SCO-267.



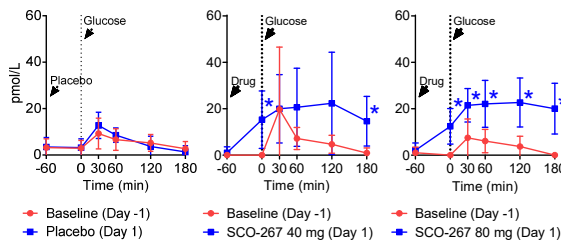
A Plasma glucose



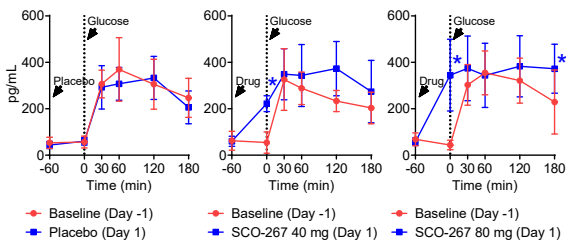
B Plasma insulin



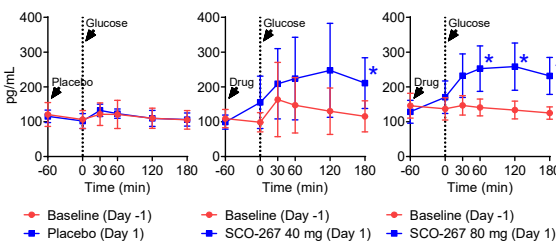
C Plasma GLP-1



D Plasma GIP



E Plasma PYY



F Plasma glucagon

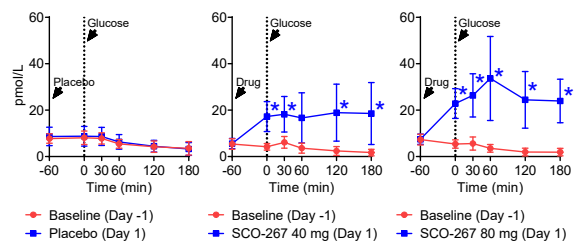


Figure. Schematic representation of therapeutic relevance of SCO-267 and effects of a single oral dose of SCO-267 on glycemic control during the oral glucose tolerance test in diabetic patients.

(n=4, 6, and 6 for placebo, SCO-267 40 mg, and 80 mg, respectively). *95% confidence interval did not cross zero at the indicated time points; SCO-267 versus placebo using the baseline (day-1)-adjusted value. Mean±SD.

References

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- 2 Furukawa, H. *et al.* Design and Identification of a GPR40 Full Agonist (SCO-267) Possessing a 2-Carbamoylphenyl Piperidine Moiety. *J Med Chem* **63**, 10352-10379, doi:10.1021/acs.jmedchem.0c00843 (2020).
- 3 Ookawara, M., Matsuda, K., Watanabe, M. & Moritoh, Y. The GPR40 Full Agonist SCO-267 Improves Liver Parameters in a Mouse Model of Nonalcoholic Fatty Liver Disease without Affecting Glucose or Body Weight. *J Pharmacol Exp Ther* **375**, 21-27, doi:10.1124/jpet.120.000046 (2020).
- 4 Ueno, H. *et al.* SCO-267, a GPR40 Full Agonist, Improves Glycemic and Body Weight Control in Rat Models of Diabetes and Obesity. *J Pharmacol Exp Ther* **370**, 172-181, doi:10.1124/jpet.118.255885 (2019).
- 5 Insulin and glucagon are secreted by pancreatic islet, and glucagon-like peptide-1 (GLP-1), glucose-dependent insulinotropic peptide (GIP), and peptide YY (PYY) by enteroendocrine cells, to regulate metabolism and body weight.

About SCOHIA PHARMA, Inc.:

SCOHIA PHARMA, Inc. is a drug discovery bioventure focusing on the field of lifestyle-related diseases such as cardiovascular, metabolic, and renal diseases. 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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SCOHIA PHARMA:

Corporate Communication

info@scohia.com