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Gilead Sciences, Novo Nordisk to collaborate for NASH trial

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The companies are also exploring the potential to collaborate on preclinical research to advance understanding of the disease.

Gilead Sciences and Novo Nordisk have announced that the companies intend to collaborate on a clinical trial combining compounds from their respective pipelines in nonalcoholic steatohepatitis (NASH). The intended clinical trial will be a proof of concept study combining Novo Nordisk's semaglutide (GLP-1 analogue) and Gilead's cilofexor (FXR agonist) and firsocostat (ACC inhibitor) for the treatment of patients with NASH. The companies are also exploring the potential to collaborate on preclinical research to advance understanding of the disease.

NASH is a chronic and progressive liver disease characterized by fat accumulation and inflammation in the liver, which can lead to scarring or fibrosis, that impairs liver function. If left untreated, individuals living with NASH may face serious consequences, including end-stage liver disease, liver cancer and the need for liver transplantation, and are at a significantly higher risk of liver-related mortality.

"NASH is a complex disease that often affects people with diabetes and metabolic syndrome. Currently, patients living with NASH have limited treatment options. We are excited to work with Novo Nordisk on this important collaboration, which would bring together Novo Nordisk's broad expertise related to diabetes and metabolism and Gilead's expertise in both liver disease and combination therapies," said John McHutchison, AO, MD, Chief Scientific Officer and Head of Research and Development at Gilead Sciences. "We look forward to working with the Novo Nordisk team to explore opportunities to advance our complementary research capabilities and approaches in NASH to help address this significant unmet need for patients."

“We are very pleased about the potential to enter into this clinical collaboration with Gilead, which would combine Novo Nordisk’s semaglutide program in NASH with Gilead’s clinical programs to provide novel approaches for the treatment of NASH. By combining the leading molecular science and clinical expertise of our two companies within the rapidly expanding liver and metabolic diseases, we aim to develop innovative, new and effective combination therapies to help people with NASH,” said Mads Krogsgaard Thomsen, Chief Science Officer and Executive Vice President of Novo Nordisk.

Cilofexor and firsocostat, alone or in combination, are investigational compounds and are not approved by the U.S. Food & Drug Administration (FDA) or any other regulatory authority. Safety and efficacy have not been established for these agents. Semaglutide has not been approved by the FDA or any other regulatory authority for the treatment of patients living with NASH.