Gilead and Novo Nordisk Expand NASH Clinical Collaboration

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– ***Triple Combination Regimen to be Investigated in New Phase 2b Study in NASH Patients with Cirrhosis*** –

FOSTER CITY, Calif. & BAGSVÆRD, Denmark--(BUSINESS WIRE)--Mar. 18, 2021-- Gilead Sciences, Inc. (Nasdaq: GILD) and Novo Nordisk A/S (Nasdaq Copenhagen: NOVO B) today announced that the companies have expanded their clinical collaboration in non-alcoholic steatohepatitis (NASH).

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20210318005315/en/

The companies will conduct a Phase 2b double-blind, placebo-controlled study to investigate the safety and efficacy of Novo Nordisk's semaglutide, a GLP-1 receptor agonist, and a fixed-dose combination of Gilead's investigational FXR agonist cilofexor and investigational ACC inhibitor firsocostat, alone and in combination in people with compensated cirrhosis (F4) due to NASH. The four-arm study in approximately 440 patients will evaluate the treatments' impact on liver fibrosis improvement and NASH resolution and will begin recruitment in the second half of 2021.

This new Phase 2b study builds on positive results from a Phase 2a proof-of-concept study presented at the Liver Meeting Digital Experience™ in November 2020 investigating semaglutide, alone and in combination with cilofexor and/or firsocostat, in 108 people with NASH and mild to moderate fibrosis. The study met its primary endpoint, demonstrating that all regimens were well tolerated over 24 weeks. The most common adverse events were gastrointestinal. Across all groups, 5–14% of people discontinued any trial treatment due to adverse events.

In addition, post-hoc analyses of exploratory efficacy endpoints assessing biomarkers of liver health at 24 weeks showed statistically significant improvements in hepatic steatosis (measured by magnetic resonance imaging proton density fat fraction; MRI-PDFF) and liver injury (measured by serum alanine aminotransferase; ALT) in the combination treatment arms versus semaglutide alone. Liver stiffness and the Enhanced Liver Fibrosis (ELF) score declined in all groups; however, statistically significant differences between groups were not observed.

"NASH is a disease with a high unmet medical need, as no drugs are currently approved to treat this potentially life-threatening condition. Building on the positive results from our proof-of-concept trial, we hope together with Gilead to demonstrate the potential for semaglutide with cilofexor and firsocostat to help people living with NASH," said Martin Holst Lange, Executive Vice President and Head of Development at Novo Nordisk.

"Gilead is pleased to expand our collaboration with Novo Nordisk and advance understanding of the potential for combination approaches in treating people living with cirrhosis due to NASH," said Mark Genovese, MD, Senior Vice President, Inflammation Clinical Development at Gilead Sciences. "This study is the latest example of our persistent focus on driving innovation to improve the lives of people living with liver diseases and fibrosis."

Cilofexor and firsocostat are investigational compounds and are not approved by the U.S. Food & Drug Administration (FDA) or any other regulatory authority. Their safety and efficacy have not been established. Semaglutide has not been approved by the FDA or any other regulatory authority for the treatment of patients living with NASH but has been approved for the treatment of type 2 diabetes.

About NASH

NASH is a chronic and progressive liver disease characterised by fat accumulation and inflammation in the liver, which can lead to scarring or fibrosis, that impairs liver function. The risk of progression to advanced liver disease, including liver decompensation (loss of liver function) and liver cancer, is higher in people with NASH than in the general population and NASH could become the leading reason for liver transplants in most countries. Currently, no pharmacotherapy is globally approved for the treatment of NASH, and people with NASH are left with very few management options.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 45,000 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

Gilead Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the risk that Gilead may not realize any anticipated benefits from this collaboration; difficulties or unanticipated expenses in connection with the collaboration and the potential effects on Gilead's revenues and earnings; the ability of the parties to initiate and complete clinical trials involving semaglutide, cilofexor and firsocostat in the anticipated timelines or at all; the possibility of unfavorable results from ongoing and additional clinical trials, including other Gilead trials involving cilofexor and firsocostat; the possibility that Gilead may make a strategic decision to discontinue development of cilofexor and firsocostat; and the possibility that the parties may make a strategic decision to terminate this collaboration at any time. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

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