Gilead and Novo Nordisk Present New Data from Proof-of-Concept Trial in NASH

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-- Results from First Phase 2 Trial Describing a Triple Combination Regimen Targeting NASH Presented at The Liver Meeting Digital Experience --

FOSTER CITY, Calif. & BAGSVÆRD, Denmark--(BUSINESS WIRE)--Nov. 15, 2020-- Gilead Sciences, Inc. (Nasdaq: GILD) and Novo Nordisk A/S (NASDAQ Copenhagen: NOVO B) today announced results from a Phase 2 proof-of-concept trial. The five-arm trial evaluated combinations of Novo Nordisk's semaglutide, a GLP-1 receptor agonist, with Gilead's investigational FXR agonist cilofexor and/or Gilead's investigational ACC inhibitor firsocostat over 24 weeks in 108 people with non-alcoholic steatohepatitis (NASH). The results were presented at The Liver Meeting Digital Experience™ (TLMdX), November 13–16, 2020 (Late Breaker #L02).

The trial met its primary endpoint by demonstrating that in people with NASH and mild to moderate fibrosis all regimens were well tolerated. The most common adverse events (AEs) were gastrointestinal. Minimal pruritus (itching) was observed in people treated with cilofexor. Across all groups, 5–14% of people discontinued any trial treatment due to AEs. Exploratory efficacy endpoints assessing biomarkers of liver health at 24 weeks in post-hoc analyses 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 arms versus semaglutide alone. Although liver stiffness measured by vibration-controlled transient elastography (VCTE) and enhanced liver fibrosis (ELF) score declined in all groups, statistically significant differences between groups were not observed.

"These results offer novel insights around the multiple mechanisms that drive NASH and demonstrate the potential of combination approaches for patients in significant need of a treatment option for this condition," said Naim Alkhouri, MD, Director of the Fatty Liver Program, Chief of Transplant Hepatology, Arizona Liver Health, Chandler. "We are encouraged that these data showcase the potential for combination approaches to elicit improvements in liver fat content, liver biochemistry, and certain non-invasive tests of fibrosis, all of which have been associated with meaningful histologic improvement in NASH."

"Gilead is focused on delivering scientific advances that can improve the lives of people with liver disease, both through our own innovation and in partnership with companies with complementary expertise, such as Novo Nordisk," said Mark Genovese, MD, Senior Vice President, Inflammation Clinical Development at Gilead Sciences. "These data offer new insights into potential therapeutic approaches to treating NASH, a disease which currently has limited treatment options."

"This trial brings together Gilead and Novo Nordisk's respective expertise and science to provide important insights into potential new combination therapies involving semaglutide to help people living with NASH," said Martin Holst Lange, Senior Vice President, Global Development at Novo Nordisk. "We are now carefully evaluating next steps together based on a thorough assessment of data."

The companies are also presenting preclinical data supporting the development of combination approaches in NASH. In the preclinical trial, semaglutide alone and in combination with cilofexor and/or GS-834356 (an analog of firsocostat) were administered daily for 12 weeks in a murine model of diet-induced NASH (n=15-16/group). The results demonstrated that while semaglutide significantly improved NASH and fibrosis-related endpoints, the addition of either cilofexor or the firsocostat analog further improved liver fat reduction. The combination of all three agents had the greatest impact on changes in the NAFLD Activity Score (NAS).

The safety and efficacy of firsocostat, GS-834356 and cilofexor have not been established. Firsocostat, GS-834356 and cilofexor are investigational compounds and are not approved by the FDA or any other regulatory authority. Semaglutide has not been approved by the FDA or any other regulatory authority for the treatment of people living with NASH, but has been approved for the treatment of type 2 diabetes.

About NASH

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. 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 research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations 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 44,000 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 Statement

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 possibility of unfavorable results from ongoing and additional clinical trials involving cilofexor, firsocostat and GS-834356 and the possibility that Gilead may be unable to complete one or more of such trials in the currently anticipated timelines or at all. Further, it is possible that Gilead may make a strategic decision to discontinue development of cilofexor, firsocostat and GS-834356 and other

investigational compounds, or that the parties may make a strategic decision to discontinue their collaboration at any time, and as a result, the compounds may never be successfully commercialized. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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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For more information about Gilead, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@Gilead Sciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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