Gilead Presents New Data in Nonalcoholic Steatohepatitis (NASH) at the International Liver Congress™ 2019

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-- New Proof-of-Concept Data for Combination of Investigational FXR Agonist Cilofexor and ACC Inhibitor Firsocostat in NASH --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 11, 2019-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced new data from the company's clinical research program in nonalcoholic steatohepatitis (NASH) being presented at The International Liver Congress™ 2019 in Vienna. The data support Gilead's efforts to develop combination therapies to target different aspects of NASH, evaluate the utility of noninvasive tests for the identification of patients living with the disease and advance overall understanding of the complexities and burden of NASH.

"NASH is a complex disease with multiple biological pathways that influence its progression. Combination therapeutic approaches which target these pathways, are likely to be needed to effectively treat patients living with NASH, particularly those with advanced fibrosis who have the greatest unmet need," said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research and Development, Gilead Sciences. "We are encouraged by the results of our proof-of-concept study being presented this week and look forward to sharing further combination data from the Phase 2 ATLAS trial later this year."

Combination Therapy Treatment for NASH

A proof-of-concept study demonstrated that the combination of the investigational, selective, non-steroidal farnesoid X receptor (FXR) agonist cilofexor (GS-9674) and the acetyl-CoA carboxylase (ACC) inhibitor firsocostat (GS-0976) resulted in improvements in hepatic steatosis, liver stiffness, liver biochemistry and serum fibrosis markers. In the study, 20 patients with NASH received cilofexor 30 mg and firsocostat 20 mg orally once daily for 12 weeks. A significant decline of at least 30 percent in hepatic fat measured by magnetic resonance imaging-proton density fat fraction (MRI-PDFF) from baseline to 12 weeks was observed in 74 percent of patients. Improvements in liver biochemistry tests including serum ALT (median relative reduction, -37%; $p<0.001$) and GGT (-32%; $p<0.001$), along with markers of reduced bile acid synthesis, were observed at 12 weeks. Treatment was well tolerated and pruritus was not reported in any patients. Asymptomatic, Grade 3 hypertriglyceridemia was observed in two patients. No patients withdrew from the study due to adverse events.

Noninvasive Tests

Liver biopsy is currently the reference standard to identify patients with NASH but is an invasive and costly procedure with potential for serious complications. Gilead will present an analysis of screening data from its Phase 2 ATLAS study evaluating combinations of investigational cilofexor, firsocostat and selonsertib in advanced fibrosis due to NASH.

This analysis demonstrates that the use of currently available noninvasive tests (NITs) can accurately identify patients with advanced fibrosis due to NASH and potentially reduce the need for liver biopsy. When used in combination, the Enhanced Liver Fibrosis (ELF) test and FibroScan® accurately identified advanced fibrosis in >80 percent of patients.

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.

Burden of Disease and Patient-Reported Outcomes

While NASH can have non-specific symptoms, research is needed to understand the impact of disease on quality of life for those living with the condition, measured through patient-reported outcomes (PROs). Baseline data from the STELLAR Phase 3 trials showed significant burden of disease among people with advanced fibrosis due to NASH. In 1,667 patients enrolled in the STELLAR trials, PROs assessed using tools including the Chronic Liver Disease Questionnaire (CLDQ-NASH) prior to treatment, particularly those related to physical health-related scores, were significantly lower than those of population norms. In another analysis of patients enrolled in the STELLAR program, diabetes mellitus was associated with impairment in PROs including physical functioning, bodily pain, general health and vitality. An additional study assessing health-related quality of life in 1,338 patients with advanced fibrosis due to NASH demonstrated that these individuals have more impairment of their physical health-related scores than patients with chronic hepatitis C virus.

About Gilead's Clinical Programs in 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. Individuals living with fibrosis are at a significantly higher risk of liver-related mortality and all-cause mortality.

Gilead is advancing multiple novel investigational compounds for the treatment of advanced fibrosis due to NASH, evaluating single-agent and combination therapy approaches against the core pathways associated with NASH – hepatocyte lipotoxicity, inflammation and fibrosis. Investigational compounds in development include the ASK1 inhibitor selonsertib, the selective, non-steroidal FXR agonist cilofexor (GS-9674) and the ACC inhibitor firsocostat (GS-0976). The STELLAR-3 Phase 3 trial evaluating selonsertib among NASH patients with bridging fibrosis (F3) is ongoing. Cilofexor and firsocostat are currently in Phase 2 studies in NASH, including the ATLAS trial evaluating combinations of selonsertib, cilofexor and firsocostat in advanced fibrosis (F3 and F4) due to NASH.

Selonsertib is an investigational compound and is not approved by the U.S. Food & Drug Administration (FDA) or any other regulatory authority.

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. For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

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 Gilead's ability to complete its clinical trial programs evaluating single-agent and combination therapy approaches, including selonsertib, cilofexor and/or firsocostat, in patients with NASH in the currently anticipated timelines or at all. In addition, there is the possibility of unfavorable results from further clinical trials involving these compounds. Further, it is possible that Gilead may make a strategic decision to discontinue development of selonsertib, cilofexor and/or firsocostat if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, the compounds may never be successfully commercialized. 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, 2018, 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.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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