Gilead Presents Proof-of-Concept Data for GS-0976 in Nonalcoholic Steatohepatitis (NASH) at The International Liver Congress™ 2017

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-- 12-Week Results with the Investigational ACC Inhibitor Show Inhibition of De Novo Lipogenesis and Significant Reductions in Liver Fat and Stiffness --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 21, 2017-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced results from an open-label, proof-of-concept study evaluating GS-0976, an investigational inhibitor of Acetyl-CoA carboxylase (ACC), in patients with nonalcoholic steatohepatitis (NASH). The data, from ten patients treated with GS-0976 20 mg taken orally once daily for 12 weeks, indicated that treatment was associated with statistically significant improvements in liver fat content and noninvasive markers of fibrosis, via inhibition of hepatic *de novo* lipogenesis (DNL). The late-breaking data were presented today during a general session at The International Liver Congress™ 2017 in Amsterdam (#GS-009).

“The identification of novel strategies for reducing liver fibrosis is a core focus in the development of therapies for patients with NASH,” said Eric J. Lawitz, MD, lead study author and Vice President of Scientific and Research Development, Texas Liver Institute and Clinical Professor of Medicine, University of Texas Health, San Antonio. “We know that elevated DNL is a major contributor to the pathogenesis of NASH and these data suggest that decreasing DNL through inhibition of ACC can lead to significant reductions in both liver fat content and stiffness, with early decreases in markers of liver fibrosis.”

Based on a novel approach involving the labeling of newly synthesized palmitate by deuterated water administration, patients receiving GS-0976 experienced a median decrease of 29 percent in hepatic DNL from baseline after 12 weeks. At week 12, patients receiving GS-0976 experienced a 43 percent median relative decrease in liver fat content, from 15.7 percent to 9.0 percent (p=0.006), as measured by magnetic resonance imaging-proton density fat fraction (MRI-PDFF). Median liver stiffness, a noninvasive marker of fibrosis, declined from 3.4 to 3.1 kPa at week 12 (p=0.049), as assessed by magnetic resonance elastography (MRE). In addition, patients with reductions in hepatic fat demonstrated improvements in liver biochemistry and serum markers of fibrosis and apoptosis, supporting the biological activity of GS-0976.

All adverse events were Grade 1 or 2 in severity. No patients prematurely discontinued study medication.

Preclinical data from a mouse model of NASH are also being presented at The International Liver Congress demonstrating that GS-0976 reduces hepatic steatosis, liver biochemistry and the expression of pro-fibrotic and pro-inflammatory genes in the liver (#FRI-352).

GS-0976 is an investigational therapy and has not been determined to be safe or efficacious.

A separate Phase 2, randomized, double-blind, placebo-controlled trial evaluating GS-0976 in 125 patients with NASH is ongoing. ACC catalyzes the first step in DNL, the synthesis of fatty acids that contributes to hepatic steatosis (fatty infiltration) and, subsequently, inflammation and liver fibrosis. ACC also regulates beta oxidation, the burning of fat by hepatic mitochondria.

About NASH

NASH is a chronic liver disease associated with steatosis, or accumulation of fat within the liver, that can lead to inflammation, progressive fibrosis and cirrhosis. The median survival for a NASH patient with cirrhosis (F4) is approximately five years.

About Gilead’s Clinical Programs in NASH

Gilead is advancing multiple novel investigational compounds for the treatment of NASH with advanced fibrosis. Gilead is currently planning or conducting Phase 2 and Phase 3 clinical trials evaluating single-agent and combination therapy approaches against multiple core pathways associated with NASH – metabolic dysregulation, inflammation and fibrosis. Compounds in development include the apoptosis signal-regulating kinase 1 (ASK1) inhibitor, selonsertib; the selective, non-steroidal Farnesoid X receptor (FXR) agonist, GS-9674; and GS-0976, an inhibitor of ACC. Phase 3 trials evaluating selonsertib among NASH patients with bridging fibrosis (F3) or cirrhosis (F4) are ongoing (the STELLAR program). GS-9674 and GS-0976 are currently in Phase 2 NASH studies.

Selonsertib, GS-9674 and GS-0976, alone and in combination, are investigational therapies and have not been determined to be safe or efficacious.

About Gilead Sciences

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

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 Phase 2 and Phase 3 clinical trial programs evaluating GS-0976, selonsertib and GS-9674 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 GS-0976, selonsertib and GS-9674 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, 2016, 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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