Gilead to Present Clinical and Preclinical Data on Nonalcoholic Steatohepatitis (NASH) at The International Liver Congress™ 2017

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-- Data Underscore Role of Liver Fibrosis as a Key Driver of NASH Clinical Disease Progression --

-- Additional Data from Phase 2 Selonsertib Study and Preclinical Combination Data with Selonsertib and GS-9674 also to be Presented --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 20, 2017-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that it will present data from 15 abstracts on the pathogenesis and treatment of NASH this week at The International Liver Congress™ 2017 in Amsterdam. This includes data Gilead will present during the opening session of the congress, which indicate that fibrosis is the primary determinant of NASH clinical disease progression (#GS-004). Gilead will also present data on investigational compounds targeting distinct mechanisms of action being studied individually, and as combination therapies, for the treatment of 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.

While found to be ineffective for reducing liver fibrosis in patients with NASH, Phase 2b studies of simtuzumab, have generated important data on the clinical progression of the disease. These analyses indicate that the primary determinant of progression to cirrhosis in patients with bridging fibrosis or to events of hepatic decompensation in patients with cirrhosis is the fibrosis stage at baseline, and its change over time. Data from the simtuzumab studies also show that modest weight loss (≥5 percent of body weight), observed in approximately 10 percent of patients, does not reduce progression to cirrhosis in NASH patients with bridging fibrosis, and that weight loss did not prevent hepatic decompensation in patients with cirrhosis (#SAT-318, #THU-362).

“These analyses provide important insights into the natural history of NASH, especially among patients with advanced disease,” said Arun J. Sanyal, MD, lead study author and Professor of Medicine, Physiology and Molecular Pathology, School of Medicine at Virginia Commonwealth University. “The results indicate that liver fibrosis is a key focus for therapeutic intervention.”

“NASH patients with advanced fibrosis or cirrhosis face the greatest risk of clinical complications and have the most urgent need for therapeutic options,” said Norbert Bischofberger, PhD, Executive Vice President of Research and Development and Chief Scientific Officer at Gilead. “Clinical trials across Gilead’s NASH pipeline are focused on this patient group, with the goal of reversing fibrosis and reducing disease progression in patients with advanced fibrosis.”

Selonsertib Studies

Several abstracts to be presented at the conference provide new insight into the potential of selonsertib, an investigational apoptosis signal-regulating kinase 1 (ASK1) inhibitor, in NASH patients with advanced fibrosis. Additional analyses from an open-label Phase 2 study of selonsertib indicate that improvement in liver fibrosis observed with selonsertib treatment was associated with consistent reductions in several noninvasive measures, including markers of liver cell death and inflammation (#PS-090), liver stiffness as assessed by magnetic resonance elastography (MRE) and liver fat as assessed by MRI-proton density fat fraction (PDFF) (#SAT-489, #SAT-483). Patients with fibrosis regression due to selonsertib also reported improved patient-reported outcomes (#PS-092). Collectively, these data demonstrate the consistency of the anti-fibrotic effects of selonsertib and highlight the potential of noninvasive assessment in monitoring response to treatment. An additional analysis from this study to be presented during an oral session also demonstrated accelerated aging based on an epigenetic clock, that is associated with the severity of fibrosis in patients with NASH (#PS-093).

Combination Therapy Data

Gilead will also present data from a preclinical study for an investigational combination of NASH therapies targeting different mechanisms of action. In a mouse model of NASH, treatment with the combination of an ASK1 inhibitor and GS-9674, an investigational non-steroidal Farnesoid X receptor (FXR) agonist, demonstrated greater reduction in hepatic steatosis and in the expression of genes associated with fibrosis compared to either agent alone (#PS-030). The preclinical data also demonstrate that ASK1 and FXR help regulate independent pathways contributing to NASH, supporting the investigation of the combination of selonsertib and GS-9674 in patients with NASH.

Further information about the clinical studies described above can be found at www.clinicaltrials.gov.

About Gilead's Clinical Programs in NASH

Gilead is advancing a pipeline of novel investigational therapies 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 an ASK1 inhibitor, selonsertib; an FXR agonist, GS-9674; and GS-0976, an inhibitor of Acetyl-CoA Carboxylase (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 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 selonsertib, GS-9674 and GS-0976 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, GS-9674 and GS-0976 if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. As a result, selonsertib, GS-9674 and GS-0976 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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