Gilead Announces Positive Phase 2 Results for GS-9674 in Primary Sclerosing Cholangitis (PSC) at The Liver Meeting® 2018

November 9, 2018

– GS-9674 Granted Orphan Drug Designation by the U.S. Food and Drug Administration –

SAN FRANCISCO--(BUSINESS WIRE)--Nov. 9, 2018-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that treatment with GS-9674, an investigational, selective, nonsteroidal farnesoid X receptor (FXR) agonist, led to significant improvements in liver biochemistry and markers of cholestasis in patients with primary sclerosing cholangitis (PSC). Data were presented at The Liver Meeting® 2018 in San Francisco.

PSC is a rare, chronic condition that causes the network of ducts that drain bile from the liver to become inflamed and scarred over time. Progressive damage to the bile ducts in patients with PSC can lead to cirrhosis, liver failure, and cholangiocarcinoma (cancer of the bile ducts). Fatigue, pruritus and abdominal discomfort are common symptoms of PSC that can greatly impact patients' quality of life. There are no approved treatments for PSC.

"Gilead is committed to applying our research expertise in liver disease to address this debilitating condition which may lead to serious liver-related complications for PSC patients," said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research and Development, Gilead Sciences. "These latest results from our Phase 2 program of GS-9674 are a positive step forward in the search for effective therapy."

In the Phase 2, double-blind, placebo-controlled trial, 52 non-cirrhotic patients with PSC were randomized to receive GS-9674 100 mg (n=22), GS-9674 30 mg (n=20), or placebo (n=10) orally once daily for 12 weeks. After 12 weeks of treatment, patients receiving GS-9674 100 mg demonstrated significant improvements in liver biochemistry tests, with a median reduction in serum alkaline phosphatase (ALP) of 20.5 percent vs. an increase of 3.4 percent with placebo (p=0.029), median reduction in gamma-glutamyl transferase (GGT) of 30.3 percent vs. an increase of 1.1 percent with placebo (p<0.001), median reduction in alanine aminotransferase (ALT) of 49.4 percent vs. 12.9 percent with placebo (p=0.009), and a median reduction in aspartate aminotransferase (AST) of 42.3 percent vs. 10.8 percent with placebo (p=0.019). In both groups treated with GS-9674, reduced serum levels of C4, an intermediate in the synthesis of bile acids, were observed compared with placebo (-23.2 percent in the 100 mg group, p=0.21; and -30.5 percent in the 30 mg group, p=0.024). Reductions in serum bile acids were greatest with the 100 mg dose.

GS-9674 was well tolerated and the incidence of Grade 2 or 3 pruritus was numerically lower with GS-9674 100 mg (13.6 percent) and 30 mg (20 percent) compared with placebo (40 percent). There were no elevations in serum lipids. Treatment was discontinued due to adverse events in three patients treated with GS-9674 100 mg (14 percent), including one discontinuation due to pruritus, and one patient with placebo (10 percent).

A separate analysis of health-related patient-reported outcome measures (PROs) among patients enrolled in the Phase 2 trial demonstrated significant impairment of PRO scores among PSC patients with pruritus or fatigue. In the evaluation, patients treated with GS-9674 100 mg experienced significant improvement of the Primary Biliary Cholangitis – 40 (PBC-40) Emotional score (p=0.04) compared with patients treated with placebo.

"Patients living with PSC urgently need effective and tolerable treatment options," said Michael Trauner, MD, presenting author and Head of the Division of Gastroenterology and Hepatology at the Medical University of Vienna, Austria. "These Phase 2 results are encouraging in terms of beneficial changes in liver biochemistry, markers of bile acid homeostasis, and patient-reported outcome measures. We look forward to further determining the safety and efficacy of this investigational agent."

GS-9674 is an investigational compound and is not approved by the U.S. Food & Drug Administration (FDA) or any other regulatory authority. Its safety and efficacy have not been determined.

About GS-9674

GS-9674 is an investigational, selective, non-steroidal agonist of the farnesoid X receptor (FXR), a nuclear hormone receptor that is highly expressed in the gastrointestinal tract and liver. FXR is the primary regulator of bile acid synthesis and plays important roles in glucose and lipid metabolism. GS-9674 is being investigated for the treatment of PSC, primary biliary cholangitis (PBC), and advanced fibrosis due to nonalcoholic steatohepatitis (NASH), a chronic and progressive liver disease characterized by fat accumulation and inflammation in the liver, which can lead to scarring or fibrosis. GS-9674 is an investigational agent and its efficacy and safety have not been determined.

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 the clinical trial programs evaluating GS-9674 for the treatment of primary sclerosing cholangitis in the currently anticipated timelines, or at all. In addition, there is the possibility of unfavorable results from additional clinical trials involving GS-9674. Further, it is possible that Gilead may make a strategic decision to discontinue development of GS-9674, and as a result, GS-9674 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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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