Gilead to Present Wide-Ranging New Data on Treatment and Diagnosis of Liver Diseases at The Liver Meeting® 2018

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-- More Than 50 Abstracts Across NASH, PSC, HBV and HCV Reflect Ongoing Commitment to Advancing the Care of People with Liver Disease--

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 11, 2018-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that data from the company's liver disease research and development programs in nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC), hepatitis B virus (HBV) infection and hepatitis C virus (HCV) infection will be presented at The Liver Meeting® 2018 in San Francisco from November 9-13, 2018. The data reflect Gilead's ongoing commitment to advancing the care of patients with serious liver diseases.

"Gilead has transformed the treatment of viral liver diseases with innovative medicines that have cured HCV and significantly improved treatment of HBV for millions around the world," said John McHutchison, AO, MD, Chief Scientific Officer, Head of Research & Development, Gilead Sciences. "Today, we are working to bring this expertise and commitment to other serious liver diseases with significant unmet medical needs, such as advanced fibrosis due to NASH and PSC – two diseases with no or limited treatment options."

Advanced Fibrosis due to NASH

Individuals with advanced fibrosis, defined as bridging fibrosis (F3) or cirrhosis (F4), are at a significantly higher risk of liver-related mortality. Gilead is advancing multiple investigational compounds for the treatment of advanced fibrosis due to NASH. Data being presented at the meeting further elucidate the potential role and safety profile of three compounds in development.

- The non-steroidal FXR agonist GS-9674 leads to significant reductions in hepatic steatosis, serum bile acids, and liver biochemistry in a Phase 2, randomized, placebo-controlled trial of patients with NASH (poster #0736)
- Hepatic metabolomics and plasma microRNA analysis of combinations of an ASK1 inhibitor, an ACC inhibitor, and an FXR agonist in the rat choline-deficient high fat diet model reveal reductions in oxidative stress, inflammation and fibrosis (poster #1265)

Currently, liver biopsy is the standard method to diagnose advanced fibrosis due to NASH. This invasive and costly procedure presents challenges to appropriate diagnosis and treatment. Data being presented at The Liver Meeting describe the potential role and sequence of noninvasive tests in the diagnosis of advanced fibrosis due to NASH and patient-reported outcomes from two global Phase 3 trials evaluating the investigational ASK1 inhibitor selonsertib.

- Algorithms using noninvasive tests can accurately identify patients with advanced fibrosis due to NASH: Data from STELLAR clinical trials (late-breaking poster #LB-10)
- Routinely available noninvasive tests discriminate advanced fibrosis due to NASH in the Phase 3 STELLAR trials of the ASK1 inhibitor selonsertib (poster #1674)
- Severe impairment of patient-reported outcomes in patients with advanced fibrosis due to NASH (poster #1683)
- Advanced fibrosis based on noninvasive tests in NASH is associated with impairment of patient-reported outcomes (poster #1991)

PSC

Data will be presented from a Phase 2 trial evaluating the investigational non-steroidal farnesoid X receptor (FXR) agonist GS-9674 in PSC. PSC is a rare and chronic condition that causes inflammation and scarring of the bile ducts, which can lead to liver failure. There are limited treatment options currently available for patients with PSC.

- The non-steroidal FXR agonist GS-9674 improves liver biochemistry and decreases serum bile acids in patients with PSC: A Phase 2, randomized, placebo-controlled trial (oral presentation #0043)

HBV Functional Cure

Data will also be presented from Gilead's ongoing program directed at achieving a functional cure for HBV by maintaining viral suppression without ongoing therapy. GS-9688, an investigational oral selective toll-like receptor 8 (TLR8) agonist, is the subject of several studies to be presented, including first-in-human clinical results and Phase 1b results from evaluation in patients with chronic hepatitis B.

- First in human study of GS-9688, an oral Toll-like Receptor 8 (TLR8) agonist, in healthy volunteers: assessment of safety, tolerability, pharmacokinetics, pharmacodynamics and food effect (poster #0390)
- Pharmacodynamic response to oral administration of the selective toll-like receptor 8 agonist GS-9688 in healthy volunteers (poster #0456)
- Safety, pharmacokinetics and pharmacodynamics of oral TLR8 agonist GS-9688 in patients with chronic hepatitis B: a randomized, placebo-controlled, double-blind Phase 1b study (poster #0401)

GS-9674, selonsertib and GS-9688 are investigational compounds and are not approved by the U.S. Food and Drug Administration (FDA) or any other

regulatory authority. Their safety and efficacy have not been established.

Viral Hepatitis Treatment

Viral hepatitis presentations include studies of Epclusa® (sofosbuvir 400mg/velpatasvir 100mg) and Harvoni® (ledipasvir 90mg/sofosbuvir 400mg) in difficult to cure HCV populations and data demonstrating the role of Vemlidy® (tenofovir alafenamide 25mg, TAF) in the management of chronic hepatitis B.

- Sofosbuvir/velpatasvir for 12 weeks is safe and effective in patients undergoing dialysis (late-breaking poster #LB-15)
- Ledipasvir/sofosbuvir for 12 weeks is safe and effective in children 3 to <6 years old with chronic HCV infection (oral presentation #0184)
- Three year efficacy and safety of TAF compared to tenofovir disoproxil fumarate (TDF) in HBeAg-negative and HBeAg-positive patients with chronic hepatitis B (poster #0404)
- Safety and efficacy at 1 year in post liver transplant patients with chronic kidney disease receiving tenofovir alafenamide for HBV prophylaxis (poster #1225)

EPCLUSA and HARVONI are each indicated in the U.S. for the treatment of chronic HCV infection in patients with no cirrhosis or compensated cirrhosis: EPCLUSA for adults with genotypes 1-6; and HARVONI for patients 12 years and older with genotypes 1, 4, 5 and 6. VEMLIDY is indicated for the treatment of chronic HBV infection in adults with compensated liver disease. The US product labels for EPCLUSA, HARVONI, and VEMLIDY each contain a BOXED WARNING: for EPCLUSA and HARVONI, the risk of hepatitis B reactivation in HCV/HBV co-infected patients; and for VEMLIDY, the risk of post-treatment acute exacerbation of HBV. See below for U.S. Important Safety Information.

The safety and efficacy of EPCLUSA in HCV patients undergoing dialysis and HARVONI in HCV patients ages 3 to up to 6 years of age have not been established.

For more information, including a complete list of abstract titles at the meeting, please visit: http://www.aasld.org/events-professional-development/liver-meeting.

US Important Safety Information and Indications for Harvoni and Epclusa

BOXED WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN HCV/HBV COINFECTED PATIENTS

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with HARVONI or EPCLUSA. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct acting antivirals (DAAs) and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Cases have been reported in patients who are HBsAg positive, in patients with serologic evidence of resolved HBV, and also in patients receiving certain immunosuppressant or chemotherapeutic agents; the risk of HBV reactivation associated with treatment with HCV DAAs may be increased in patients taking these other agents. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

Contraindications

If HARVONI or EPCLUSA is used in combination with ribavirin (RBV), all contraindications, warnings and precautions, in particular pregnancy avoidance, and adverse reactions to RBV also apply. Refer to RBV prescribing information.

Warnings and Precautions

Serious Symptomatic Bradycardia When Coadministered with Amiodarone: Amiodarone is not recommended for use with HARVONI or EPCLUSA due to the risk of symptomatic bradycardia, particularly in patients also taking beta blockers or with underlying cardiac comorbidities and/or with advanced liver disease. A fatal cardiac arrest was reported in a patient taking amiodarone who was coadministered a sofosbuvir containing regimen. In patients without alternative, viable treatment options, cardiac monitoring is recommended. Patients should seek immediate medical evaluation if they develop signs or symptoms of bradycardia.

Risk of Reduced Therapeutic Effect Due to Use with P-gp Inducers and/or Moderate to Potent Inducers of CYP: Rifampin, St. John's wort and carbamazepine are not recommended for use with HARVONI or with EPCLUSA. P-gp inducers may significantly decrease ledipasvir, sofosbuvir and/or velpatasvir plasma concentrations. Moderate to potent inducers of CYP2B6, CYP2C8 or CYP3A4 may significantly decrease sofosbuvir and/or velpatasvir plasma concentrations.

Adverse Reactions

The most common adverse reactions (≥10%, all grades) with HARVONI were fatigue, headache, and asthenia.

The most common adverse reactions (≥10%, all grades) with EPCLUSA were headache and fatigue; and when used with RBV in decompensated cirrhotics were fatigue, anemia, nausea, headache, insomnia, and diarrhea.

Drug Interactions

HARVONI: Coadministration is not recommended withoxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, and tipranavir/ritonavir due to decreased concentrations of ledipasvir and sofosbuvir; or with co-formulated elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate due to increased concentrations of tenofovir; or with simeprevir due to increased concentrations of ledipasvir and simeprevir; or with rosuvastatin due to increased concentrations of rosuvastatin.

EPCLUSA: Coadministration is not recommended with topotecan due to increased concentrations of topotecan; or with proton-pump inhibitors,

oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, efavirenz, and tipranavir/ritonavir due to decreased concentrations of sofosbuvir and/or velpatasvir.

Consult the full Prescribing Information for HARVONI and EPCLUSA for more information on potentially significant drug interactions, including clinical comments.

INDICATION for HARVONI

HARVONI is indicated for the treatment of adults with chronic hepatitis C virus genotype (GT) 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis. HARVONI is used with ribavirin in GT 1 adults with decompensated cirrhosis and in GT 1 or 4 adult liver transplant recipients without cirrhosis or with compensated cirrhosis.

INDICATION for EPCLUSA

EPCLUSA is indicated for the treatment of adults with chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis and in combination with ribavirin for those with decompensated cirrhosis.

US Important Safety Information and Indications for Vemlidy

BOXED WARNING: POST TREATMENT SEVERE ACUTE EXACERBATION OF HEPATITIS B

Discontinuation of anti-hepatitis B therapy, including VEMLIDY, may result in severe acute exacerbations of hepatitis B. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VEMLIDY. If appropriate, resumption of anti-hepatitis B therapy may be warranted.

Warnings and Precautions

Risk of Development of HIV-1 Resistance in HBV/HIV-1 Coinfected Patients: Due to this risk, VEMLIDY alone should not be used for the treatment of HIV-1 infection. Safety and efficacy of VEMLIDY have not been established in HBV/HIV-1 coinfected patients. HIV antibody testing should be offered to all HBV-infected patients before initiating therapy with VEMLIDY, and, if positive, an appropriate antiretroviral combination regimen that is recommended for HBV/HIV-1 coinfected patients should be used.

New Onset or Worsening Renal Impairment: Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of VEMLIDY, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue VEMLIDY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Monitor renal function in all patients – See Dosage and Administration.

Lactic Acidosis and Severe Hepatomegaly with Steatosis: Fatal cases have been reported with the use of nucleoside analogs, including tenofovir disoproxil fumarate. Discontinue VEMLIDY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse Reactions

Most common adverse reactions (incidence ≥5%; all grades) were headache, abdominal pain, cough, back pain, fatigue, nausea, arthralgia, diarrhea, and dyspepsia.

Drug Interactions

Coadministration of VEMLIDY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir and the risk of adverse reactions.

Coadministration of VEMLIDY is not recommended with the following: oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, or St. John’s wort. Such coadministration is expected to decrease the concentration of tenofovir alafenamide, reducing the therapeutic effect of VEMLIDY. Drugs that strongly affect P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) activity may lead to changes in VEMLIDY absorption.

Consult the full prescribing information for VEMLIDY for more information on potentially significant drug interactions, including clinical comments.

Dosage and Administration

Dosage: Adults; 1 tablet taken once daily with food.

Renal Impairment, Screening, and Monitoring: VEMLIDY is not recommended in patients with CrCl <15 mL/min. In all patients, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein prior to initiating and during treatment, on a clinically appropriate schedule. In patients with chronic kidney disease, also assess serum phosphorus.

Hepatic Impairment: Not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment.

Testing Prior to Initiation: HIV infection.

INDICATION

VEMLIDY is indicated for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease.

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 35

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 the possibility of unfavorable results from ongoing and additional clinical trials involving GS-9674, selonsertib and GS-9688. Further, it is possible that the parties may make a strategic decision to discontinue development of GS-9674, selonsertib and GS-9688, and as a result, these 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 Quarterly Report on Form 10-Q for the quarter ended June 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.

*U.S. Full Prescribing Information for Epclusa, Harvoni and Vemlidy including **BOXED WARNINGS**, are available at www.gilead.com.*

Epclusa, Harvoni and Vemlidy are registered trademarks of Gilead Sciences, Inc., or its related companies.

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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Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Investors
Sung Lee, 650-524-7792
or
Media
Arran Attridge, 650-425-8975