Gilead Sciences to Present New Hepatitis B and C Data at European Conference on Liver Disease This Week

April 18, 2012 7:33 AM ET

- Presentations Include First Results For Lead Hepatitis C Candidate GS-7977 In Treatment-Naïve Genotype 1 Patients -

BARCELONA, Spain, Apr 18, 2012 (BUSINESS WIRE) --Gilead Sciences, Inc. (Nasdaq:GILD) today announced that 30 abstracts examining the company's products and investigational agents for hepatitis B and C have been selected for presentation at the 47th Annual Meeting of the European Association for the Study of the Liver (International Liver Congress 2012) taking place April 18-22 in Barcelona, Spain. The abstracts describe clinical and preclinical data for a number of investigational chronic hepatitis C compounds, as well as new long-term data for Viread(R) (tenofovir disoproxil fumarate) for chronic hepatitis B.

Presentations will include data from several studies examining Gilead's late-stage nucleotide analog polymerase inhibitor, GS-7977, in treatment-naïve genotype 1 hepatitis C patients. Genotype 1 is the most prevalent strain of the hepatitis C virus (HCV), and also the hardest to treat with existing therapies. Data from ELECTRON (Poster #1113) and ATOMIC (Oral Abstract #1) will be presented and both studies have been selected for inclusion in official EASL Press Office activities.

In addition to GS-7977, Gilead is advancing multiple oral compounds with different mechanisms of action with the goal of creating an efficacious, well tolerated and convenient all-oral treatment regimen for chronic HCV. Notably, data will be presented for two of these compounds, GS-5885 (an NS5A inhibitor) and GS-9669 (a non-nucleoside polymerase inhibitor):

- Interim efficacy and safety results for a Phase 2 study (Study 120) examining 12 weeks of treatment with GS-5885, GS-9451, tegobuvir (GS-9190) and ribavirin. Based on the results of this trial and other studies involving more than 800 patients treated with GS-5885 for at least 12 weeks, Gilead has selected a 90 mg dose of GS-5885 for further clinical development (Latebreaker Poster #1421).
- Results of a three-day, Phase 1, ascending-dose study, which demonstrate the potent antiviral activity of GS-9669, a non-nucleoside polymerase inhibitor, when administered once-daily (Poster #1189).

Seven abstracts at the International Liver Congress will highlight the safety and efficacy profile of Viread, the most-prescribed treatment for chronic hepatitis B in the United States and major countries of Europe. Notably, new data further characterize Viread's well-established renal safety profile:

- The VIREAL prospective cohort study reports on 115 chronic hepatitis B patients with reduced renal function at baseline, the majority of whom either remained stable or improved after 48 weeks of treatment with Viread (Poster #531).

Abstracts for Gilead's presentations can currently be accessed on the EASL website, with the exception of the ELECTRON and ATOMIC studies, which are embargoed until Thursday, April 19, 2012 due to their inclusion in the press program of the International Liver Congress. Gilead will issue press releases describing the data from these studies. Further information about these studies can also be found at www.clinicaltrials.gov.

GS-7977, GS-5885, GS-9669, GS-9451 and tegobuvir (GS-9190) are investigational products and their safety and efficacy have not yet been established.

Important Information About Viread for Chronic Hepatitis B

Viread (tenofovir disoproxil fumarate) is indicated for the treatment of chronic hepatitis B in adults. The following points should be considered when initiating therapy with Viread for the treatment of HBV infection: This indication is based primarily on data from the treatment of nucleoside-treatment-naïve patients, and a smaller number of patients who had previously received lamivudine or adefovir. Patients were adults with HBeAg-positive and HBeAg-negative chronic hepatitis B with compensated liver disease. Viread was evaluated in a limited number of subjects with chronic hepatitis B and decompensated liver disease. The number of patients in clinical trials who had lamivudine- or adefovir-associated substitutions at baseline was too small to reach conclusions of efficacy.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleos(t)ide analogs, including Viread, in combination with other antiretrovirals.

Severe acute exacerbations of hepatitis have been reported in HBV-infected patients who have discontinued anti-hepatitis B therapy, including Viread. 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 Viread. If appropriate, resumption of anti-hepatitis B therapy may be warranted.

New onset or worsening of renal impairment including cases of acute renal failure and Fanconi syndrome has been reported with the use of Viread. It is recommended to assess creatinine clearance (CrCl) before initiating treatment with Viread and monitor CrCl and serum phosphorus in patients at risk, including those who have previously experienced renal events while receiving Hepsera(R). Administering Viread with concurrent or recent use of nephrotoxic drugs should be avoided.

Viread should not be used with other tenofovir-containing products (e.g., Atripla(R), Complera(R), Truvada(R)). Viread should not be administered in combination with Hepsera.

Due to the risk of development of HIV-1 resistance, Viread should only be used as part of an appropriate antiretroviral combination regimen in HIV-infected patients with or without HBV coinfection. HIV antibody testing should be offered to all HBV-infected patients before initiating therapy with Viread.

Decreases in bone mineral density (BMD) have been observed in HIV-infected patients. It is recommended that BMD monitoring be considered for patients with a history of pathologic fracture or who are at risk for osteopenia. The bone effects of Viread have not been studied in patients with chronic HBV infection. Cases of osteomalacia (associated with proximal renal tubulopathy and which may contribute to fractures) have been reported in association with the use of Viread.

In controlled clinical trials in patients with chronic hepatitis B with compensated liver disease, the most common adverse reaction (all grades) was nausea, observed in 9 percent of patients taking Viread at week 48. Other adverse reactions observed at week 48 in greater than 5 percent of patients treated with Viread include abdominal pain, diarrhea, headache, dizziness, fatigue, nasopharyngitis, back pain and skin rash.

In HBV-infected patients with decompensated liver disease, the most common adverse reactions (all grades) reported in greater-than or equal to 10 percent of patients treated with Viread were abdominal pain (22 percent), nausea (20 percent), insomnia (18 percent), pruritus (16 percent), vomiting (13 percent), dizziness (13 percent), and pyrexia (11 percent).

Coadministration of Viread with didanosine increases didanosine concentrations. Use with caution and monitor for evidence of didanosine toxicity (e.g., pancreatitis, neuropathy). Didanosine should be discontinued in patients who develop didanosine-associated adverse reactions. In adults weighing >60 kg, the didanosine dose should be reduced to 250 mg when it is coadministered with Viread. Data are not available to recommend a dose adjustment of didanosine for patients weighing <60 kg. Coadministration of Viread with atazanavir decreases atazanavir concentrations and increases tenofovir concentrations. Use atazanavir with Viread only with additional ritonavir; monitor for evidence of tenofovir toxicity. Coadministration of Viread with lopinavir/ritonavir increases tenofovir concentrations. Monitor for evidence of tenofovir toxicity.

The recommended dose for the treatment of chronic hepatitis B is 300 mg once daily taken orally without regard to food. The dosing interval of Viread should be adjusted and renal function closely monitored in patients with moderate and severe renal impairment.

The parent compound of Viread was discovered through a collaborative research effort between Dr. Antonin Holy, Institute for Organic Chemistry and Biochemistry, Academy of Sciences of the Czech Republic (IOCB) in Prague and Dr. Erik DeClercq, Rega Institute for Medical Research, Katholic University in Leuven, Belgium.

Please see full Prescribing Information for Viread, Atripla, Complera, Truvada and Hepsera (including BOXED WARNINGS).

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 worldwide. Headquartered in Foster City, California, Gilead has operations in North America, Europe and Asia Pacific.

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 subsequent results in studies examining GS-7977, GS-5885, GS-9669, GS-9451 and tegobuvir (GS-9190). As a result, these compounds may never be successfully commercialized. In addition, Gilead may make a strategic decision to discontinue development of these compounds if, for example, Gilead believes commercialization will be difficult relative to other opportunities in its pipeline. Further, Gilead may be unable to develop an all-oral antiviral regimen for HCV genotype 1 patients or a pangenotypic regimen for all HCV patients. 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, 2011, 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 Viread is available at www.Viread.com.
U.S. full prescribing information for Atripla is available at www.Atripla.com.
U.S. full prescribing information for Complera is available at www.Complera.com.
U.S. full prescribing information for Truvada is available at www.Truvada.com.
U.S. full prescribing information for Hepsera is available at www.Hepsera.com.

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

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