European CHMP Adopts Positive Opinion for Gilead's Epclusa® (Sofosbuvir/Velpatasvir) for the Treatment of All Genotypes of Chronic Hepatitis C

May 27, 2016 7:27 AM ET

--Epclusa is Gilead's Third Sofosbuvir-Based Treatment to Receive a CHMP Positive Opinion for the Treatment of Chronic HCV Infection--

FOSTER CITY, Calif.--(BUSINESS WIRE)--May 27, 2016-- Gilead Sciences, Inc. (NASDAQ:GILD) today announced that the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has adopted a positive opinion on the company's Marketing Authorization Application (MAA) for Epclusa®, an investigational, pan-genotypic, once-daily tablet containing the nucleotide analogue polymerase inhibitor sofosbuvir (SOF) 400 mg and velpatasvir (VEL) 100 mg, an investigational pan-genotypic NS5A inhibitor, for the treatment of chronic hepatitis C virus (HCV) infection. The data included in the application support the use of Epclusa (SOF/VEL) in adults with all genotypes (GT1-6) of HCV infection.

The CHMP positive opinion was adopted following an accelerated review procedure, reserved for medicinal products expected to be of major public health interest. The recommendation will now be reviewed by the European Commission, which has the authority to approve medicines for use in the 28 countries of the European Union, Norway and Iceland.

The MAA for Epclusa is supported by data from four Phase 3 studies, ASTRAL-1, ASTRAL-2, ASTRAL-3 and ASTRAL-4. In the ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies, 1,035 patients with genotypes 1-6 HCV infection, without cirrhosis or with compensated cirrhosis (Child-Pugh A) received 12 weeks of Epclusa. The ASTRAL-4 study randomized 267 patients with genotypes 1-6 HCV infection, with decompensated cirrhosis (Child-Pugh B) to receive 12 weeks of Epclusa with or without ribavirin (RBV) or 24 weeks of Epclusa. The primary endpoint for each study was sustained virologic response 12 weeks after completing therapy (SVR12).

Of the 1,035 patients treated with Epclusa for 12 weeks in the ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies, 1,015 (98 percent) achieved SVR12. In ASTRAL-4, patients with decompensated cirrhosis receiving Epclusa with RBV for 12 weeks achieved a high SVR12 rate (94 percent) compared to those who received Epclusa for 12 weeks or 24 weeks without RBV (83 percent and 86 percent, respectively). The most common adverse events in the four ASTRAL studies were headache, fatigue and nausea, and were comparable in incidence to the placebo group included in ASTRAL-1.

Sofosbuvir as a single agent was granted marketing authorization in the European Union on January 16, 2014, under the trade name Sovaldi®. The fixed-dose combination of sofosbuvir and ledipasvir received marketing authorization in the European Union on November 18, 2014, under the trade name Harvoni®.

Gilead has also submitted a regulatory application for SOF/VEL in the United States. Gilead filed the NDA for SOF/VEL on October 28, 2015, and the Food and Drug Administration (FDA) has set a target action date under the Prescription Drug User Fee Act (PDUFA) of June 28, 2016.

Epclusa is an investigational product and its safety and efficacy has not yet been established.

About Gilead

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 the risk that the European Commission or other regulatory agencies, including the FDA, may not approve SOF/VEL for the treatment of chronic hepatitis C and that any marketing approvals, if granted, may have significant limitations on its use. As a result, Gilead may not be able to successfully commercialize SOF/VEL for chronic hepatitis C. 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 March 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.

Full European Summary of Product Characteristics for Sovaldi and Harvoni are available from the EMA website at www.ema.europa.eu

Epclusa, Sovaldi and Harvoni 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 1-650-574-3000.

View source version on businesswire.com: http://www.businesswire.com/news/home/20160527005292/en/

Source: Gilead Sciences, Inc.

Gilead Sciences, Inc.
Investors
Sung Lee, +1 650-524-7792
or
Media (Europe)
Arran Attridge, +44 208-587-2477
or
Media (U.S.)
Cara Miller, +1 650-522-1616