Gilead Announces SVR12 Rates From Four Phase 3 Studies of a Once-Daily, Fixed-Dose Combination of Sofosbuvir, Velpatasvir and Voxilaprevir in Treatment-Naïve and Treatment-Experienced Genotype 1-6 Chronic HCV-Infected Patients

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- If Approved, SOF/VEL/VOX Would Be the First Once-Daily Single Tablet Regimen Available for Salvage for Patients Who Have Failed Prior HCV Therapy with Oral Direct-Acting Antiviral Agent Regimens -

- U.S. NDA Planned for Q4 2016 -

FOSTER CITY, Calif.--(BUSINESS WIRE)--Oct. 20, 2016-- Gilead Sciences, Inc. (NASDAQ: GILD) today announced topline results from four international Phase 3 clinical studies (POLARIS-1, POLARIS-2, POLARIS-3 and POLARIS-4) evaluating an investigational, once-daily, fixed-dose combination of sofosbuvir (SOF), a nucleotide analog NS5B polymerase inhibitor; velpatasvir (VEL), a pangenotypic NS5A inhibitor; and voxilaprevir (VOX; GS-9857), an investigational pangenotypic NS3/4A protease inhibitor, for the treatment of genotype 1-6 chronic hepatitis C virus (HCV) infection.

In the POLARIS-1 and POLARIS-4 studies, 445 patients with genotype 1-6 HCV infection who were previously treated with direct-acting antiviral agents (DAAs) received 12 weeks of SOF/VEL/VOX. The POLARIS-1 study enrolled patients who failed prior treatment with an NS5A inhibitor. The POLARIS-4 study enrolled patients who failed prior treatment with a DAA that was not an NS5A inhibitor, most with either an NS5B inhibitor alone (73 percent) or an NS5B inhibitor and an NS3/4A protease inhibitor (25 percent).

In the POLARIS-2 and POLARIS-3 studies, 611 patients who were not previously treated with a DAA received 8 weeks of SOF/VEL/VOX. The POLARIS-2 study enrolled patients with genotype 1-6 HCV infection with or without compensated cirrhosis. The POLARIS-3 study enrolled patients with genotype 3 HCV infection, all of whom had compensated cirrhosis.

The primary endpoint for all studies was SVR12. The intent-to-treat SVR12 rates observed in the POLARIS studies are summarized in the following table. Complete results from all four studies will be presented at The Liver Meeting® 2016 in Boston.

Study	Population	Genotype	Treatment	Duration	SVR12 Rates
POLARIS-1	NS5A inhibitor-experienced 41 percent (172/415) had cirrhosis	1, 2, 3, 4, 5, 6	SOF/VEL/VOX	12 Weeks	96% (253/263)
			Placebo	12 Weeks	0% (0/152)
POLARIS-4	DAA-experienced (No NS5A inhibitor) 46 percent (153/333) had cirrhosis	1, 2, 3, 4	SOF/VEL/VOX	12 Weeks	97% (177/182)
			SOF/VEL	12 Weeks	90% (136/151)
POLARIS-2	DAA-naïve	1, 2, 3, 4, 5, 6	SOF/VEL/VOX	8 Weeks	95% (476/501)

	18 percent (174/941) had cirrhosis		SOF/VEL	12 Weeks	98% (432/440)
	DAA-naïve		SOF/VEL/VOX	8 Weeks	96% (106/110)
POLARIS-3		3			
	All had cirrhosis		SOF/VEL	12 Weeks	96% (105/109)

Patients treated with SOF/VEL/VOX for 12 or eight weeks had similar overall incidence of adverse events compared to placebo-treated or SOF/VEL-treated patients. The most common adverse events among patients who received SOF/VEL/VOX were headache, fatigue, diarrhea and nausea. Among the 1,056 patients who received SOF/VEL/VOX in the four studies, one patient (less than one percent) receiving SOF/VEL/VOX for 12 weeks discontinued due to an adverse event.

“Despite recent advances that have provided high cure rates and simplified treatment for most HCV patients, those who have failed previous treatment with direct acting antivirals continue to represent an unmet medical need. The POLARIS study results demonstrate that combining three potent antivirals with different mechanisms of action and high barriers to resistance can provide high cure rates for patients who have failed other highly effective oral DAA regimens,” said Norbert Bischofberger, Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer at Gilead. “Based on these Phase 3 results, we plan to submit regulatory applications for SOF/VEL/VOX for the treatment of chronic HCV in the United States in the fourth quarter of 2016 and shortly thereafter in Europe.”

About the POLARIS Studies

The POLARIS-1 study was a double-blind, placebo-controlled study in 415 genotype 1-6 NS5A inhibitor-experienced patients. The most common prior NS5A inhibitors were ledipasvir (55 percent) and daclatasvir (23 percent).

The open-label POLARIS-4 study evaluated the use of SOF/VEL/VOX or SOF/VEL for 12 weeks in 333 genotype 1-4 HCV-infected patients with prior DAA experience that did not include an NS5A inhibitor. Most patients (85 percent) had prior DAA experience with sofosbuvir.

The open-label POLARIS-2 study evaluated the use of SOF/VEL/VOX for eight weeks or SOF/VEL for 12 weeks in 941 genotype 1-6 DAA-naïve HCV-infected patients, including 18 percent with cirrhosis and 23 percent who had previously failed treatment with an interferon-based regimen.

The open-label POLARIS-3 study randomized patients with genotype 3 HCV infection and cirrhosis to receive SOF/VEL/VOX daily for eight weeks or SOF/VEL for 12 weeks. Of the 219 patients treated, 31 percent had previously failed treatment with an interferon-based regimen.

The POLARIS-1, POLARIS-3 and POLARIS-4 studies met their respective pre-specified primary endpoints for the patients receiving SOF/VEL/VOX. The POLARIS-2 study did not meet its primary endpoint; with a pre-specified 5 percent margin, the SVR12 rate for patients receiving treatment with SOF/VEL/VOX for eight weeks was not statistically non-inferior to the SVR12 rate for patients receiving SOF/VEL for 12 weeks.

About SOF/VEL/VOX

The SOF/VEL/VOX fixed-dose combination is an investigational product and its safety and efficacy have not been established. It has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration for the treatment of chronic genotype 1 HCV patients who have previously failed an NS5A inhibitor-containing regimen.

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 the risk that future trials involving the SOF/VEL/VOX fixed-dose combination may have unfavorable results. In addition, Gilead may be unable to file for U.S. regulatory approval of the SOF/VEL/VOX fixed-dose combination in the United States and Europe in the currently anticipated timelines. In addition, the FDA and other regulatory agencies may not approve the SOF/VEL/VOX fixed-dose combination, and any marketing approvals, if granted, may have significant limitations on its use. 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, 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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