Gilead Announces SVR12 Rates from Four Phase 3 Studies Evaluating a Once-Daily, Fixed-Dose Combination of Sofosbuvir (SOF) and Velpatasvir (VEL) (GS-5816) for the Treatment of All Six Hepatitis C Genotypes

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- If Approved, SOF/VEL Would be the First All-Oral Pan-Genotypic Single Tablet Regimen for Chronic HCV-

- U.S. NDA and European MAA Submissions Planned for Q4 2015 -

FOSTER CITY, Calif.--(BUSINESS WIRE)--Sep. 21, 2015-- Gilead Sciences, Inc. (Nasdaq:GILD) today announced topline results from four international Phase 3 clinical studies (ASTRAL-1, ASTRAL-2, ASTRAL-3 and ASTRAL-4) evaluating a once-daily, fixed-dose combination of the nucleotide analog polymerase inhibitor sofosbuvir (SOF) with velpatasvir (VEL), an investigational pangenotypic NS5A inhibitor, for the treatment of genotype 1-6 chronic hepatitis C virus (HCV) infection.

In the ASTRAL-1, ASTRAL-2, and ASTRAL-3 studies, 1,035 patients with genotype 1-6 HCV infection received 12 weeks of SOF/VEL. Among these patients, 21 percent had compensated cirrhosis and 28 percent had failed prior treatments. The ASTRAL-4 study randomized 267 patients with decompensated cirrhosis (Child-Pugh class B) to receive 12 weeks of SOF/VEL with or without ribavirin (RBV), or 24 weeks of SOF/VEL. The primary endpoint for all studies was SVR12.

The intent-to-treat SVR12 rates observed in the ASTRAL studies are summarized in the table below. Complete results from all four studies will be presented at future scientific conferences.

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>N</th>
<th>Treatment</th>
<th>Duration</th>
<th>SVR12 Rates</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Overall: 99%</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>(618/624)</td>
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<td>GT1: 98%</td>
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<td>(323/328)</td>
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<tr>
<td>ASTRAL-1</td>
<td>Genotypes 1,2,4,5,6</td>
<td>624</td>
<td>SOF/VEL</td>
<td>12 weeks</td>
<td>99% (121/121)</td>
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<td>19 percent (121/624) with cirrhosis</td>
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<td>116 patients received placebo</td>
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<td></td>
<td>(SVR12=0%)</td>
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<tr>
<td>ASTRAL-2</td>
<td>Genotype 2</td>
<td>134</td>
<td>SOF/VEL</td>
<td>12 weeks</td>
<td>99% (133/134)</td>
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<td></td>
<td>14 percent (38/266) with cirrhosis</td>
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<tr>
<td>ASTRAL-3</td>
<td>Genotype 3</td>
<td>277</td>
<td>SOF/VEL</td>
<td>12 weeks</td>
<td>95% (264/277)</td>
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<tr>
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<td>30 percent (163/552) with cirrhosis</td>
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<tr>
<td>ASTRAL-4</td>
<td>Genotypes 1-6</td>
<td>87</td>
<td>SOF/VEL+RBV</td>
<td>12 weeks</td>
<td>94% (82/87)</td>
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of Sofosbuvir (SOF) and Velpatasvir (VEL) (GS-5816) for the Treatment of All Six Hepatitis C Genotypes
Of the 1,035 patients treated with SOF/VEL for 12 weeks in the ASTRAL-1, ASTRAL-2 and ASTRAL-3 studies, 1,015 (98 percent) achieved the primary efficacy endpoint of SVR12. Of the 20 patients who did not achieve SVR12, 13 patients (1.3 percent) experienced virologic failure and seven did not complete an SVR12 visit (e.g., lost to follow-up). Twelve of the 13 virologic failure patients relapsed (two genotype 1 HCV-infected patients and 10 genotype 3 HCV-infected patients). There was one patient with documented reinfection. No patients with genotype 2, 4, 5 or 6 HCV infection had virologic failure.

Patients treated with SOF/VEL for 12 weeks in these three studies had similar adverse events compared with placebo-treated patients in ASTRAL-1. Two patients (0.2 percent) treated with SOF/VEL for 12 weeks, one each in ASTRAL-1 and ASTRAL-2, discontinued treatment due to adverse events. The most common adverse events were headache, fatigue and nausea.

In ASTRAL-4, patients with Child-Pugh class B cirrhosis receiving SOF/VEL+RBV achieved higher SVR12 rates than patients receiving SOF/VEL for 12 or 24 weeks. Among genotype 1 and 3 patients treated with SOF/VEL+RBV for 12 weeks, the SVR12 rates were 96 percent and 85 percent, respectively.

The most common adverse events across all arms of ASTRAL-4 were fatigue, nausea and headache. Anemia, a common side effect associated with RBV, was reported in 31 percent of patients in the SOF/VEL+RBV arm and in 4 percent and 3 percent of patients treated with SOF/VEL for 12 or 24 weeks, respectively. Treatment emergent serious adverse events occurred in 18 percent of patients and nine patients died. The majority of serious adverse events and deaths were associated with advanced liver disease.

“The ASTRAL study results demonstrate that a 12-week course of therapy with the first fixed-dose combination of two pan-genotypic compounds can provide high cure rates for patients with all HCV genotypes,” said Norbert Bischofberger, Ph.D., Executive Vice President of Research and Development and Chief Scientific Officer at Gilead. “We are pleased to have now brought forward our second single tablet regimen for HCV infection that complements Harvoni, our first single tablet regimen approved specifically for patients with genotype 1 infection and which could eliminate the need for HCV genotype testing. We look forward to advancing the regulatory submissions for the SOF/VEL fixed-dose combination.”

The U.S. Food and Drug Administration has assigned the SOF/VEL fixed-dose combination a Breakthrough Therapy designation, which is granted to investigational medicines that may offer major advances in treatment over existing options.

The SOF/VEL fixed-dose combination is an investigational product and its safety and efficacy have not yet been established.

**About the ASTRAL Studies**

The double-blind, placebo-controlled ASTRAL-1 trial enrolled 740 patients with chronic genotype 1, 2, 4, 5 or 6 HCV infection randomized to SOF/VEL or placebo for 12 weeks.

The open-label ASTRAL-2 study evaluated the use of SOF/VEL or SOF+RBV for 12 weeks in 266 genotype 2 HCV-infected patients.

The open-label ASTRAL-3 study evaluated the use of SOF/VEL for 12 weeks or SOF+RBV for 24 weeks in 552 genotype 3 HCV-infected patients.

The ASTRAL-1 study met its primary endpoint of statistical superiority to the pre-specified SVR12 goal of 85 percent (p<0.001). ASTRAL-2 and ASTRAL-3 also met their respective endpoints. In ASTRAL-2, the SVR12 rate among
genotype 2 HCV-infected patients receiving SOF/VEL for 12 weeks was statistically superior to the SVR12 rate for patients receiving SOF+RBV for 12 weeks (p=0.018). In ASTRAL-3, the SVR12 rate among genotype 3 HCV-infected patients receiving SOF/VEL for 12 weeks was statistically superior to that of patients treated with SOF+RBV for 24 weeks (p<0.001).

The open-label ASTRAL-4 study evaluated the use of SOF/VEL with or without RBV for 12 weeks and SOF/VEL for 24 weeks in 267 HCV-infected patients with Child-Pugh class B cirrhosis, regardless of genotype.

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 Gilead may be unable to file for U.S. regulatory approval of the SOF/VEL fixed-dose combination in the currently anticipated timelines. In addition, the FDA and other regulatory agencies may not approve the SOF/VEL 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, 2015, 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 Sovaldi and Harvoni are available at [www.gilead.com](http://www.gilead.com).

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For more information on Gilead Sciences, please visit the company’s website at [www.gilead.com](http://www.gilead.com), follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.


Source: Gilead Sciences, Inc.

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