var drug_url = "ledipasvir-sofosbuvir";

Ledipasvir-Sofosbuvir *(Harvoni)*

See also
Sofosbuvir
,
Sofosbuvir-Velpatasvir
.

Table of Contents

Drug Summary

The fixed dose combination of ledipasvir-sofosbuvir provides a very attractive and effective one pill once a day option for treatment of genotypes 1, 4, 5, and 6 chronic hepatitis C infection. This regimen is the first FDA-approved interferon- and ribavirin-free regimen to treat hepatitis C. Three phase 3 trials (ION-1, ION-2, and ION-3) have demonstrated SVR rates consistently above 90%. The 24-week regimen for treatment-experienced cirrhotic patients is very expensive; recent data have shown that treatment-experienced patients with genotype 1 and compensated cirrhosis can have the regimen shortened to 12 weeks if ribavirin is added. Ledipasvir-sofosbuvir is a recommended therapy for patients with genotype 1, 4, 5, and 6 in the American Association for the Study of Liver Diseases, Infectious Diseases Society of America, (AASLD/IDSA) guidance. In addition, ledipasvir-sofosbuvir is a very attractive option for treatment of hepatitis C in persons coinfected with HIV.

Class and Mechanism

Ledipasvir is a potent inhibitor of HCV NS5A, a viral phosphoprotein that plays an important role in viral replication, assembly, and secretion. Sofosbuvir is a nucleotide analog inhibitor of hepatitis C virus NS5B polymerase—the key enzyme mediating HCV RNA replication. The triphosphate form of sofosbuvir (GS-461203) mimics the natural cellular uridine nucleotide and is incorporated by the HCV RNA polymerase into the elongating RNA primer strand, resulting in viral chain termination.

Manufacturer for United States

The fixed-dose combination of ledipasvir and sofosbuvir (*Harvoni*) (Figure 1) is manufactured by Gilead Sciences.

Cost and Medication Access

The wholesale acquisition cost (WAC) for ledipasvir-sofosbuvir is $1125 per pill.

- Cost of 8-week course of therapy = $63,000
- Cost of 12-week course of therapy = $94,500
- Cost of 24-week course of therapy = $189,000

Gilead Sciences has an active ledipasvir-sofosbuvir patient assistance program for eligible patients with hepatitis C who do not have insurance and do not have coverage through Medicaid or Medicare. Information regarding the Gilead Sciences ledipasvir-sofosbuvir (*Harvoni*) patient assistance program can be obtained at the Support Path for *Solvaldi* and *Harvoni* web site and by contacting them directly by phone at 1-855-769-7284 (hours of operation Monday through Friday between 9:00 am and 8:00 pm Eastern Time).

Adverse Effects

Available data from clinical trials has demonstrated the combination of ledipasvir-sofosbuvir has been very well tolerated. The most common reported adverse effects are fatigue and headache.

Key Drug Interactions

For complete information on ledipasvir-sofosbuvir-related drug interactions, see the Drug Interactions section in the Ledipasvir-Sofosbuvir (*Harvoni*) Prescribing Information.

Clinical Trials

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- Pharmacology

ION-1

In this open-label phase 3 trial, investigators enrolled 865 treatment-naive patients with genotype 1 chronic hepatitis C and compared a 12- and 24-week treatment course of the fixed-dose combination of ledipasvir-sofosbuvir, given with our without ribavirin. In this study, patients with compensated cirrhosis were eligible to enroll (up to 20% of the total study participants could have cirrhosis). All treatment arms had SVR12 rates greater than 95% and no differences were observed in the 12-week versus the 24-week treatment course. In addition, use of ribavirin did not improve SVR rates. Further, patients with cirrhosis had similar SVR rates as those without cirrhosis. This study clearly established that a 12-week course of the fixed-dose combination ledipasvir-sofosbuvir, without ribavirin, is highly effective in treatment-naive patients with chronic HCV genotype 1 infection, including those with cirrhosis.

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ION-2

In the ION-2 trial, investigators randomized 440 treatment-experienced patients with genotype 1 chronic hepatitis C infection to receive a 12- or 24-week treatment with fixed-dose combination ledipasvir-sofosbuvir, with or without ribavirin. Patients were considered treatment-experienced if

they had not achieved an SVR with a previous regimen of peginterferon plus ribavirin, with or without an NS3/4A protease inhibitor. For the treatment experienced patients, 41 to 46% had a prior nonresponse (null responder). Patients were allowed to enroll if they had cirrhosis, but the number of patients with cirrhosis enrolled could not exceed 20% of the total enrolled. The SVR12 rate with 12 weeks of ledipasvir-sofosbuvir was 94% without ribavirin and 96% with ribavirin. Both groups of patients who received 24 weeks of therapy had an SVR12 rate of 99%. For patients with cirrhosis, the SVR rates were lower with 12 weeks of therapy (86% with ledipasvir-sofosbuvir and 82% with ledipasvir-sofosbuvir with ribavirin) compared with the respective 95% and 100% SVR rates with 12 weeks in patients who did not have cirrhosis. The SVR rates were 99 to 100% in both treatment groups receiving 24 weeks of therapy, including those with cirrhosis. The investigators clearly established that ledipasvir-sofosbuvir is highly effective in treatment-experienced patients, even those who previously received an NS34A protease inhibitor. Treatment-experienced patients with cirrhosis may benefit by extending treatment duration from 12 to 24 weeks.

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ION-3

In this open-label phase 3 trial, investigators randomized 647 treatment-naive patients with genotype 1 chronic hepatitis C to one of three regimens that included the fixed-dose combination of ledipasvir-sofosbuvir: 8 weeks of ledipasvir-sofosbuvir, 8 weeks of ledipasvir-sofosbuvir plus ribavirin, or 12 weeks of ledipasvir-sofosbuvir. Patients with cirrhosis were not eligible to enroll. Similar SVR12 rates were observed in the three treatment arms: 94% with 8 weeks of ledipasvir-sofosbuvir, 93% with 8 weeks of ledipasvir-sofosbuvir plus ribavirin, and 95% with 12 weeks of ledipasvir-sofosbuvir. A subanalysis showed that a pre-treatment HCV RNA level less than 6 million IU/mL correlated with higher SVR12 rates in the group that received 8 weeks of ledipasvir-sofosbuvir. This study has shown that (1) ledipasvir-sofosbuvir is highly effective in treatment-naive genotype 1 patients without cirrhosis and (2) an 8-week treatment course is a reasonable and more cost-effective option for treatment-naive patients without cirrhosis if they have a baseline HCV RNA less than 6 million IU/mL.

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ION-4

In this phase 3, open-label, multicenter study in the United States, Canada, and New Zealand, investigators enrolled 335 patients with hepatitis C and HIV coinfection to receive a 12-week course of ledipasvir-sofosbuvir. Enrollment included genotype 1 or 4 HCV treatment-naive and experienced patients without cirrhosis and those with compensated cirrhosis. The HIV enrollment criteria consisted of HIV RNA less than 50 copies/ml and CD4 count greater than 100 cells/mm^3. The antiretroviral regimens that were allowed consisted of tenofovir-emtricitabine plus either efavirenz, rilpivirine, or raltegravir. Most (98%) of the patients enrolled had genotype 1 HCV infection and 55% were treatment experienced. Overall, 321 (96%) of 335 treated patients achieved an SVR12. The results were similar regardless of prior treatment status or presence of cirrhosis.

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ELECTRON (Arms 12-17 and 22)

In this phase 2, open-label study, which involved seven arms (12-17, and 22) of the parent

ELECTRON study, investigators compared an array of all-oral regimens, most of which included ledipasvir and sofosbuvir; six of the seven regimens included ribavirin and two included GS-9669. A total of 113 patients were enrolled in the seven arms of this study and the groups included treatment-naive noncirrhotics, treatment-experienced (with prior null response) noncirrhotics, and treatment experienced (with prior null response) cirrhotics. All of the regimens were taken for a duration of 12 weeks, except for the 6-week regimen of ledipasvir-sofosbuvir plus ribavirin, which was used in noncirrhotic treatment-naive patients. All of the groups that received ledipasvir plus sofosbuvir plus ribavirin had very high SVR rates, except for the group that received only 6 weeks of therapy. The ledipasvir plus GS-9669 plus ribavirin regimen also performed very well.

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LONESTAR

This phase 2 trial evaluated 8- and 12-week courses of the fixed-dose combination of ledipasvir (90 mg) and sofosbuvir (400 mg), with or without ribavirin (weight based dose of 1000 to 1200 mg/day divided BID) in treatment-naive and treatment experienced patients wtih chronic HCV genotype 1 infection. The study enrolled a total of 100 patients, 60 who were treatment naïve (Cohort A) and 40 who had previously failed prior therapy with an HCV protease inhibitor-based regimen (Cohort B). Among the treatment-experienced patients, 55% had documented, compensated cirrhosis. The study included 5 treatment arms and a total of 100 patients. In all of the five study arms, SVR12 was achieved in 95 to 100% of patients. The regimen of ledipasvir-sofosbuvir was well tolerated; only one patient had a serious adverse event of anemia, thought to be related to ribavirin. This study clearly showed that the fixed-dose combination of ledipasvir-sofosbuvir with or without ribavirin is highly effective in treatment-naive and treatment-experienced patients.

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New Zealand Genotype 3 and 6 Trial

In the open-label, phase 2 New Zealand Genotype 3 and 6 trial, investigators enrolled 126 patients with chronic hepatitis C infection to receive a 12 weeks of treatment with fixed-dose combination ledipasvir-sofosbuvir, with or without ribavirin. Four groups were enrolled: (a) treatment-naive patients with genotype 3 infection who received ledipasvir-sofosbuvir, (b) (a) treatment-naive patients with genotype 3 infection who received ledipasvir-sofosbuvir plus ribavirin, (c) treatment-experienced patients with genotype 3 infection who received ledipasvir-sofosbuvir plus ribavirin, and (d) treatment-naive and -experienced patients with genotype 6 infection who received ledipasvir-sofosbuvir. The SVR 12 responses in treatment-naive patients with genotype 3 were superior in the regimen with ribavirin (100%) than without ribavirin (64%). Among the treatment-experienced patients, 41 (82%) of 50 achieved an SVR 12 with a regimen of ledipasvir-sofosbuvir plus ribavirin. The SVR 12 rate was 96% in the patients with genotype 6. In this trial, the investigators showed that patients with genotype 3 had very good SVR 12 rates with ledipasvir-sofosbuvir plus ribavirin and those with genotype 6 responded well to ledipasvir-sofosbuvir plus ribavirin without ribavirin.

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NIAID ERADICATE

ERADICATE is an open-label, nonrandomized, phase 2 trial investigating the safety and efficacy of a

12-week regimen of ledipasvir-sofosbuvir in HCV treatment-naive patients with genotype 1 chronic hepatitis C who are coinfected with HIV. The study enrolled 50 patients and divided them into two cohorts: (a) those not receiving antiretroviral therapy (n=13), and (b) those receiving antiretroviral therapy (n=37). The patients on antiretroviral therapy were allowed to receive tenofovir-emtricitabine plus either efavirenz, raltegravir, rilpivirine, rilpivirine plus raltegravir, or efavirenz plus raltegravir. Data for patients not taking antiretroviral therapy showed 13 (100%) of 13 achieved an SVR12. For patients taking antiretroviral therapy, 36 (97%) of 37 achieved an SVR12. These findings suggest that ledipasvir-sofosbuvir is very effective in patients with genotype 1 HCV and HIV coinfection. The hepatitis C regimen was well tolerated and no patient discontinued hepatitis C therapy.

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NIAID Retreatment of Sofosbuvir Failures

This open-label, phase 2a trial enrolled patients with genotype 1 HCV who previously had failed a 24-week course of sofosbuvir plus ribavirin and retreated them using fixed-dose combination of ledipasvir-sofosbuvir for 12 weeks. A total of 14 patients enrolled and all had prior relapse as the cause of treatment failure. Among the 14 patients, 13 were male and 13 were black. One half of those enrolled had advanced fibrosis (Knodell Histology Activity Index score of 3 or 4). The virologic response rates were excellent, with 14 (100%) of 14 patients achieving an SVR12. This small study is very promising but should be confirmed by larger future studies, which could include prior nonresponders.

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NIAID SYNERGY (Genotype 1)

The NIAID SYNERGY (Genotype 1) trial was an open-label, phase 2a trial that enrolled 60 treatment-naive patients with genotype 1 chronic HCV to receive one of three treatment groups: (a) ledipasvir-sofosbuvir for 12 weeks; (b) ledipasvir-sofosbuvir (90-400 mg) plus the non-nucleoside NS5B inhibitor GS-9669 (500 mg once daily) for 6 weeks, or (c) ledipasvir-sofosbuvir (90-400 mg) plus the NS3/4A protease inhibitor GS-9451 (80 mg once daily) for 6 weeks. Patients in the 12-week ledipasvir-sofosbuvir arm with any stage of fibrosis could be enrolled in the study. For the other two treatment arms, patients were excluded if they had cirrhosis. Overall, patients in all three arms of the study had excellent SVR12 rates: 20 (100%) of 20 patients in the ledipasvir-sofosbuvir arm, 19 (95%) of 20 in the ledipasvir-sofosbuvir plus GS-9669 group, and 19 (95%) of 20 in the ledipasvir-sofosbuvir plus GS-9451 group. This study demonstrates that (1) patients with genotype 1 chronic HCV achieve very high SVR rates with a 12-week course of ledipasvir-sofosbuvir and (2) ledipasvir-sofosbuvir, when combined with a third direct-acting antiviral agent, is highly effective as a short-course 6 week regimen in treatment-naive patients without cirrhosis.

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NIAID SYNERGY (Genotype 4)

The NIAID SYNERGY (Genotype 4) trial was an open-label, phase 2a trial that enrolled 21 patients with genotype 4 chronic HCV to receive ledipasvir-sofosbuvir for 12 weeks. Among those enrolled, 13

(68%) were treatment-naive and 8 (32%) were treatment-experienced. The treatment-experienced patients previously had received an interferon- or peginterferon-based regimen. Patients with compensated cirrhosis were allowed to enroll in the study and 7 (33%) of 21 had cirrhosis. Overall, in the intent-to-treat analysis 20 (95%) of 21 patients achieved an SVR12. One patient, a treatment-naive patient, was considered a treatment failure and withdrew from the study at week 7 due to non-adherence with therapy.

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Retreatment of Sofosbuvir Failures from prior Clinical Trials

In this open-label, phase 2 trial, patients with genotype 1 chronic HCV who failed a sofosbuvir-containing regimen in a phase 2 or 3 Gilead-sponsored clinical trial were eligible to receive retreatment with a 12-week course of ledipasvir-sofosbuvir plus ribavirin. Patients with compensated cirrhosis were allowed to enroll in the study (27% of patients enrolled had cirrhosis). Among the patients treated with ledipasvir-sofosbuvir plus ribavirin, 50 (98%) of 51 achieved an SVR12; the one patient who failed had genotype 3 HCV and was erroneously enrolled in the trial. Overall, the 12-week regimen of ledipasvir-sofosbuvir plus ribavirin was well tolerated and it shows promise as a treatment option for patients with prior sofosbuvir failure.

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SIRIUS

This phase 2, double-blind trial compared the efficacy of a 12-week course of ledipasvir-sofosbuvir plus ribavirin versus a 24-week course of ledipasvir-sofosbuvir in treatment-experienced patients with genotype 1 HCV and compensated cirrhosis. Investigators enrolled 155 patients in the trial and all had previously sequentially failed dual therapy with peginterferon and ribavirin and triple therapy with peginterferon and ribavirin and an NS3/4A protease inhibitor. One patient dropped out of the study due to an adverse event that occurred while receiving placebo. Among patients who received a 12-week course of ledipasvir-sofosbuvir plus ribavirin, 96% achieved and SVR12 compared with 97% in the group that received a 24-week course of ledipasvir-sofosbuvir. Baseline NS5A resistant-associated variants did not significantly impact treatment response. This study suggests that in genotype 1 treatment-experienced patients with cirrhosis, a 12-week course of ledipasvir-sofosbuvir plus ribavirin provides similar SVR12 rates as a 24-week course of ledipasvir-sofosbuvir and this 12-week regimen provides a more cost-effective option.

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SOLAR-1: (Cohorts A and B)

In this phase 2, open label trial, 337 patients with HCV genotype 1 or 4 and advanced liver disease were randomized to receive either a 12-week or 24-week course of ledipasvir-sofosbuvir plus ribavirin. The study included two cohorts: the cohort A (pretransplantation) arm of the study enrolled patients with cirrhosis and moderate to severe hepatic impairment; cohort B consisted of patients who were post liver transplantation. Patients were also stratified based on no cirrhosis, Child-Turcotte-Pugh (CTP) class A, B or Class C, and fibrosing cholestatic hepatitis. In the cohort A (pre-transplant) group, the SVR12 rate was 87% in the 12-week arm and 89% in the 24-week arm. In the cohort B (post-transplant) group, SVR12 results with combined 12 and 24 week data show clearly

better in patients with less advanced liver disease: 96% in CTP A versus 87% in CTP B versus 67% in CTP C. The results were similar with either 12- or 24 weeks of treatment except for patients with CTP C: nine post-transplant patients with CTP C received therapy and SVR rates 60% with 12 weeks of therapy and 75% with 24 weeks. The treatment was well-tolerated and there were few treatment-related adverse events. The patients with virologic response had significant improvement in liver function, including improvements in bilirubin, albumin, Modified End Stage Liver Disease (MELD) scores, and Child-Turcotte-Pugh scores. These results are very promising for the treatment of patients with advanced liver disease, including post-transplantation patients, and it appears that a 12-week course is equivalent to the 24-week course, except perhaps with patients who have CTP C liver disease.

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