CME NEWSLETTER

Advances in Chronic Hepatitis C Management and Treatment

Based on an Expert Panel Review and Discussion Program from

The 63rd American Association for The Study of Liver Diseases Annual Meeting

(This coverage is not sanctioned by the conference organizers and is not an official part of the conference proceedings.)

Jointly Sponsored by the Postgraduate Institute for Medicine and ViralEd, LLC.

63rd AASLD
November 9-13, 2012
Boston, Massachusetts

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Introduction

This newsletter is based on discussions held during the continuing medical education poster review and discussion program Advances in Chronic Hepatitis C Management and Treatment. *This program provided an update on important presentations made during the 63rd American Association for the Study of Liver Diseases (AASLD) Annual Meeting.**

The faculty for this program consisted of: Douglas T. Dieterich, MD from Mount Sinai School of Medicine, New York, New York; Paul Y. Kwo, MD from Indiana University School of Medicine, Indianapolis, Indiana; Paul J. Pockros, MD from The Scripps Clinic, La Jolla, California; and Professor Jean-Michel Pawlotsky, MD, PhD, University of Paris-Est, Créteil, France.

The ELECTRON Trial

The first 5 arms of the ELECTRON trial showed that 12 weeks of treatment with sofosbuvir (SOF, formerly GS-7977) + ribavirin (RBV) were highly effective in treatment-naïve patients with genotype (GT) 2/3 hepatitis C virus (HCV). At AASLD, investigators reported on Arms 7-11, which evaluated SOF + RBV in treatment-naïve and null responder GT1 patients and treatment-experienced GT2/3 patients and determined the feasibility of regimens with a shorter duration or reduced dose of RBV in treatment-naïve GT2/3 patients **[Abst. 229]**.[1] They also reported some preliminary data about adding on the NS5A inhibitor GS-5885 to SOF + RBV.

In arms 7-11, 3 arms received SOF + RBV for 12 weeks: 10 GT1 prior null responders (Arm 7); 25 treatment-naïve GT1 patients (Arm 8); and 25 treatment-experienced GT2/3 patients (Arm 9). In addition, 25 treatment-naïve GT2/3 patients received SOF + RBV (1,000/1,200 mg) for 8 weeks (Arm 10) and 10 treatment-naïve GT2/3 patients received SOF + RBV (800 mg) for 12 weeks (Arm 11).

A total of 95 patients were enrolled in these 5 arms. Of the 10 GT1 prior null responders (Arm 7), 1 (10%) achieved SVR12; the other 9 relapsed prior to post-treatment week 4. Of the 25 treatment-naïve GT1 patients (Arm 8), 21 (84%) achieved SVR12. Of the 25 treatment-experienced GT2/3 patients (Arm 9), 17 (68%) achieved SVR12. In Arm 10, 16 (64%) treatment-naïve GT2/3 patients treated for 8 weeks achieved SVR12, and in Arm 11, 6 (60%) of treatment-naïve GT2/3 patients treated with 800 mg of RBV for 12 weeks achieved SVR8. The investigators also presented preliminary data on 25 GT1 treatment-naïve and 9 GT1 previous null responders treated with GS-5885 + SOF + RBV for 12 weeks. At the time of the meeting, 25/25 (100%) of the GT1 treatment-naïve patients had an SVR4 with this combination and 3 of 9 GT1 null responders reached the 4-week post-treatment time point and remained HCV negative. The investigators concluded

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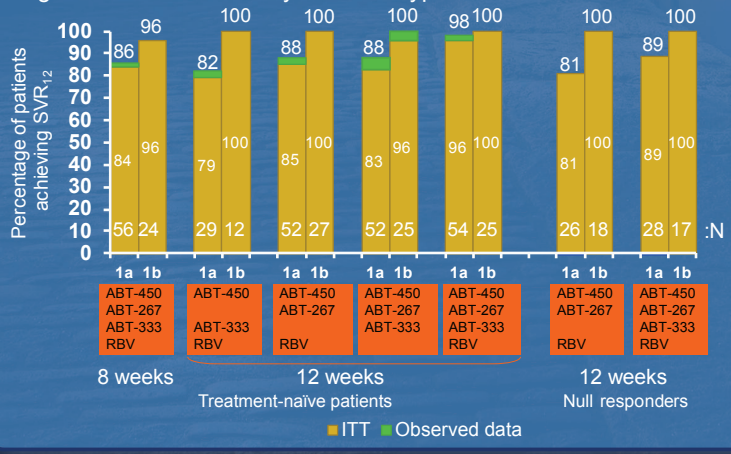
that in patients with HCV GT2 or 3 infection, SOF + RBV for 12 weeks appears to be a safe and effective regimen for both treatment-naïve and previously treated patients, although treatment durations <12 weeks or reduced RBV dose may adversely impact treatment efficacy. In patients with HCV GT1, addition of GS-5885 increased the efficacy of SOF + RBV with no additional safety or tolerability issues.

ABT-450/r, ABT-267, ABT-333 and RBV in Treatment-Naïve and Prior Null Responders with HCV GT1 Infection

ABT-450 is a HCV protease inhibitor (dosed with ritonavir, ABT-450/r). Interferon (IFN)-free ABT-450/r-based regimens showed high SVR in exploratory studies. A study presented as AASLD assessed efficacy and safety of several regimens of ABT-450/r with ABT-267 (an NS5A inhibitor) and/or ABT-333 (a non-nucleoside NS5B inhibitor) ± RBV **[Abst. LB-1]**.[2]

Non-cirrhotic treatment-naïve HCV patients and prior pegylated interferon (PegIFN)/RBV null responders received ABT-450/r with 1-2 other direct-acting antivirals (DAAs) (ABT-267 or ABT-333) ± RBV for 8, 12, or 24 weeks. 571 patients (438 treatment-naïve and 133 prior null responders) received ≥1 dose of study drug, including 448 in 8- and 12-week arms. The 12-week 3 DAA + RBV regimen had the highest SVR12 rates based on post-treatment week 12 data or earlier failure. SVR12 rates (ITT) were 97% in treatment-naïve patients and 93% in null responders. SVR12 rates for other 8- and 12-week regimens ranged from 85%-90%. The investigators concluded that 3 DAAs (ABT-450/r, ABT-267, and ABT-333) + RBV for 12 weeks was well-tolerated and

Figure 1. SVR12 Rates by HCV Subtype



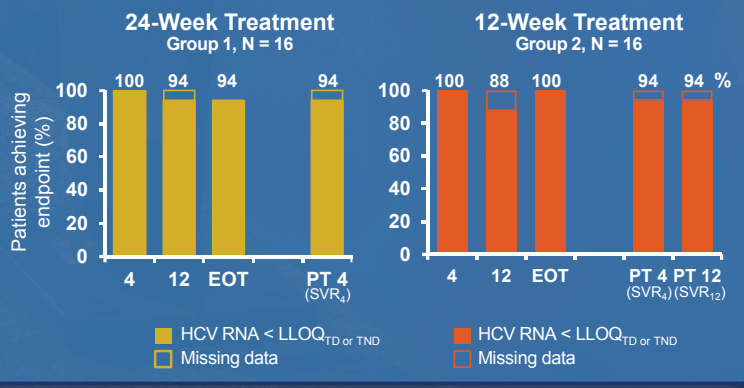
achieved high SVR12 rates in non-cirrhotic GT1-infected patients, including those with historical predictors of poor response (GT1a, IL28B non-CC, prior null response; see Figure 1).

Daclatasvir, Asunaprevir, and BMS-791325 in Treatment-Naïve Patients with GT1

Investigators evaluated the combination of the NS5A replication complex inhibitor daclatasvir (DCV), the NS3 protease inhibitor asunaprevir (ASV), and the selective non-nucleoside NS5B polymerase inhibitor BMS-791325 for 24 or 12 weeks in treatment-naïve patients with HCV GT1 infection **[Abst. LB-3]**.[3] In part 1 of this phase 2a, open-label study, 32 treatment-naïve, HCV GT1-infected, non-cirrhotic patients with baseline HCV RNA ≥105 IU/mL were randomized 1:1 to ASV 200 mg BID, DCV 60 mg QD, and BMS-791325 75 mg BID for 24 (Group 1) or 12 (Group 2) weeks. Randomization was stratified by GT1 subtype (1a/1b). In part 2, investigators randomized patients to the same DAA regimen for 24 or 12 weeks, but at a 150 mg BID dose of BMS-791325. The primary end point is HCV RNA < lower limit of quantification (LLOQ, 25 IU/mL) at 12 weeks post-treatment (SVR12).

In the modified ITT analysis, 94% of patients in Group 1 achieved SVR4, and 94% of patients in Group 2 achieved SVR12 (Figure 2). The investigators concluded that this interferon- and RBV-free triple DAA combination of DCV + ASV + BMS-791325 resulted in high rates of SVR after both 12 and 24 weeks of treatment. SVR4 was achieved in all treatment-naïve GT1 patients for whom post-treatment data were available, including harder-to-treat patients with GT1a and IL28B non-CC genotypes.

Figure 2. HCV RNA End Points (Modified ITT Analysis)



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TVR or BOC + PegIFN + RBV in Cirrhotic Non-Responders: Week 16 Analysis from CUPIC

Investigators presented the week 16 analysis of safety and efficacy of telaprevir (TVR) or boceprevir (BOC) with PegIFN + RBV in cirrhotic, experienced (relapse, partial response) patients treated in the French Early Access Program (ANRS CO20-CUPIC) **[Abst. 51]**.[4] GT1 patients with compensated cirrhosis (Child Pugh A) were prospectively included and received 12 weeks of TVR + PegIFN + RBV, then 36 weeks of PegIFN + RBV; or 4 weeks PegIFN + RBV + 44 weeks BOC + PegIFN + RBV. The analysis was restricted to 455 patients who reached week 16 of therapy. At week 16, the percentage of patients with undetectable HCV RNA for TVR was 92% (per protocol; 67% ITT) and for BOC it was 77% (per protocol; 58% ITT).

The investigators reported that in this large cohort of cirrhotics, the safety profile of the triple therapy regimen was poor compared with phase III trials (increased rates of severe adverse events [SAEs] and more difficult management of anemia) but that treatment was associated with high rates of on-treatment virologic response. Based on these findings, they recommended that the risk/benefit ratio should be assessed in cirrhotic, experienced patients with platelets counts ≤100,000/mm^3 or serum albumin levels <35 g/L. These patients should be treated on a case-by-case basis, due to high risk for developing severe complications. However, cirrhotic, experienced patients without predictors of severe complications should be treated but cautiously and carefully monitored.

Daclatasvir + Sofosbuvir ± RBV in Treatment-Naïve Patients with HCV GT1, 2, or 3

Investigators evaluated DCV + SOF ± RBV in previously untreated patients with HCV GT1, 2, or 3 **[Abst. LB-2]**.[5] This parallel-group, open-label study randomized 44 GT1 and 44 GT2 or 3 HCV-infected, non-cirrhotic patients 1:1:1 to SOF for 7 days, then DCV + SOF for 23 weeks; DCV + SOF for 24 weeks; or DCV + SOF + RBV for 24 weeks. By a protocol amendment, an additional 82 GT1 patients were randomized 1:1 to DCV + SOF ± RBV for 12 weeks. The primary end point was HCV RNA <25 IU/mL (LLOQ) at 12 weeks post-treatment (SVR12). The majority of GT1 patients (24-week arms) were GT1a (73%); GT2/3 patients were 59% GT2, 41% GT3.

Among GT1 patients, those treated for 12 weeks had an SVR4 of 96%, and all patients who reached post-treatment week 12 achieved SVR12, including 3 patients not classified as SVR4. Among GT1 patients treated for 24 weeks, SVR24 was 98%; there was one patient with re-infection post-treatment. In GT2/3 patients, SVR24 was 93%; there was one patient with confirmed relapse (GT3). Based on these findings, the investigators concluded that 24 weeks of the all-oral, once-daily combination of DCV + SOF achieved high rates of SVR in previously untreated patients with HCV genotype 1, 2, or 3. IL28B genotype, genotype 1 subtype, and the use of RBV did not influence the virologic response.

VITAL-1 Study: Alisporivir + RBV in Treatment-Naïve Patients with HCV GT2 or GT3

In VITAL-1, investigators measured SVR in patients receiving alisporivir (ALV)-based therapy – either fully IFN-free or delayed add-on PegIFN to ALV + RBV – in HCV GT2/3 patients **[Abst. 233]**.[6] In the study, 340 treatment-naïve HCV GT2 or GT3 patients (ratio 3:7) were randomized to 5 treatment arms: 1) ALV 1,000 mg QD monotherapy [ALV1000, n=83]; 2) ALV 600 mg QD + RBV [ALV600/RBV, n=84]; 3) ALV 800 mg QD + RBV [ALV800/RBV, n=94]; 4) ALV 600 mg QD + PegIFN [ALV/Peg, n=39]; or 5) PegIFN + RBV, n=40. Patients in ALV-containing arms that achieved RVR (week 4 undetectable HCV RNA <25 IU/mL) continued on the initial treatment for 24 weeks, while those with detectable HCV RNA added PegIFN from week 6 to week 24 (ALV 600/PegIFN/RBV regimen).

The SVR24 rate achieved (ITT analysis) was 80% for ALV1000, 85% for ALV600/RBV, 81% for ALV800/RBV, 80% for ALV/Peg, and 58% for PegIFN + RBV (Figure 3). There was no difference in GT2 and GT3 responses to ALV + RBV treatment. The rates of viral breakthrough in patients receiving ALV-based treatments were very low – 3% (9/299). Testing for ALV-exposure and viral resistance showed that the likely causes of viral breakthrough in these 9 patients were low ALV exposure (n=4), viral resistance (n=3), or both (n=2).

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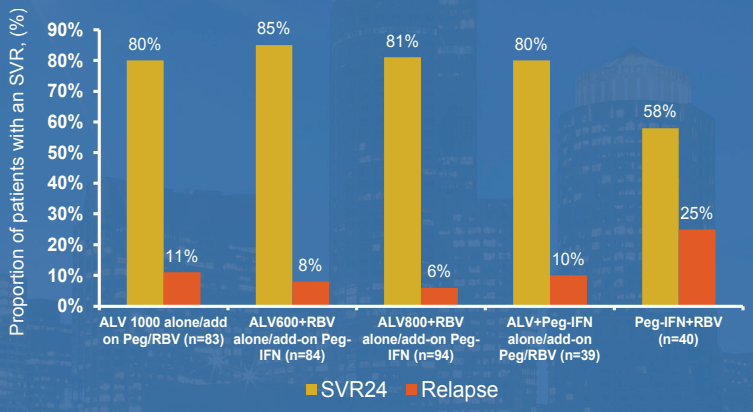
The safety profile of ALV, IFN-free was markedly better than IFN-containing regimens, with lower rates of general symptoms and laboratory abnormalities (except bilirubin) compared with IFN-containing arms. The investigators concluded that ALV + RBV represents an effective IFN-free option in HCV GT2/3 patients resulting in high SVR24 rates for patients with early viral clearance.

Figure 3. VITAL-1: Overall SVR24 (ITT Analysis)



OPTIMIZE: TVR BID vs. TVR q8h in Treatment-Naïve, GT1 HCV-infected Patients

OPTIMIZE was a phase III, randomized, open-label, non-inferiority study comparing twice daily (BID) vs. q8h TVR, both with PegIFN + RBV **[Abst. LB-8]**.[7] Treatment-naive patients with HCV GT1 infection were randomized (stratified by fibrosis stage and IL28B genotype) to 750 mg q8h or 1,125 mg BID TVR + PegIFN + RBV for 12 weeks (TVR phase), then PegIFN + RBV alone for 12 weeks if week 4 HCV RNA was <25 IU/mL (RVR), or 36 weeks if HCV RNA was detectable. The primary end point was SVR12 (HCV RNA <25 IU/mL) 12 weeks after the last planned dose of PegIFN + RBV. The pre-specified non-inferiority margin was -11%. 744 patients were randomized, of which 740 were treated. 60% of patients were male, 92% were Caucasian, 15% had bridging fibrosis, 14% had compensated cirrhosis, 85% had baseline HCV RNA ≥800,000 IU/mL, 57% had HCV GT1a, and 29% had IL28B CC.

The investigators reported that SVR12 was 74% in the TVR BID group vs. 73% in the TVR q8h group. The difference between the TVR BID and TVR q8h groups was 1.5%, with a 95% CI: -4.9 to 12.0. The lower limit of the 95% CI (-4.9%) was well above the predetermined noninferiority margin of -11% and thus established the noninferiority of TVR BID + PegIFN + RBV to TVR q8h + PegIFN + RBV. SVR12 outcomes for TVR BID and TVR q8h were similar regardless of liver fibrosis status and IL28B genotype. The adverse event (AE) profile was generally similar between arms.

BOC + PegIFN + RBV in Treatment-Naïve Chronic HCV Genotype 1 Patients with Compensated Cirrhosis: the Anemia Management Study

The Anemia Management Study was designed to determine the impact on SVR and safety of two anemia management strategies in cirrhotics vs. noncirrhotics treated with BOC + PegIFN + RBV **[Abst. 50]**.[8] Treatment-naive patients (n=687) with baseline hemoglobin (Hb) 12 to 15 g/dL (female) or 13 to 15 g/dL (male) were enrolled in a randomized, open-label trial and received 4 weeks of PegIFN + RBV, then 24 or 44 weeks of BOC + PegIFN + RBV. Patients with or approaching Hb ≤10 g/dL were randomized to receive RBV dose reduction (DR) or erythropoietin (EPO); patients who did not meet the anemia criterion continued on BOC + PegIFN + RBV without change. If Hb ≤8.5 g/dL, secondary strategies could be used (RBV DR, EPO and/or transfusion). If Hb ≤7.5 g/dL, all study drugs were discontinued.

Of the patients with biopsy results, 9% (60/664) were cirrhotic. Baseline characteristics were generally similar between cirrhotics and noncirrhotics, but cirrhotics were more likely to be male, older, and have a higher body mass index. The SVR was 55% for cirrhotics and 64% for noncirrhotics. 80% (48/60) of cirrhotics and 73% (438/604) of noncirrhotics met the protocol definition for anemia and were randomized to RBV DR or EPO. SVR in noncirrhotics was 73% (162/221) for RBV DR and 72% (157/217) for EPO. SVR in cirrhotics was 57% for RBV DR and 64% EPO. Compared to noncirrhotics, cirrhotics were more likely to require secondary intervention regardless of initial anemia management. 22% (13/60) of cirrhotics had Hb ≤8.5 g/dL vs. 11% (67/604) of noncirrhotics. Transfusions were administered to 3% (2/60) of cirrhotics (1 in each arm) and 2% (14/604) of noncirrhotics. Although cirrhotics developed anemia no more frequently than noncirrhotics, cirrhotics were more likely to have severe anemia and to require secondary interventions. The investigators stated

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that RBV dose reduction should be considered as the initial management strategy for anemia.

Simeprevir (TMC435) with PegIFN + RBV for Treatment of HCV GT1 Infection in Patients with METAVIR Scores F3 or F4 (PILLAR and ASPIRE Trials)

PILLAR and ASPIRE are two international, randomized, double-blind, placebo-controlled studies that assessed efficacy, safety, and pharmacokinetics of TMC435 – a once-daily, oral HCV NS3/4A protease inhibitor – with PegIFN and RBV in HCV GT1 patients **[Abst. 83]**.[9] Patients with METAVIR scores of F3 were included in PILLAR, and those with scores of F3/F4 were in ASPIRE. Patients were either treatment-naïve (PILLAR) or -experienced (ASPIRE) and received PegIFN + RBV alone or in combination with TMC435 for 12, 24 or 48 weeks. Total PegIFN duration was response guided (RGT; 24 or 48 weeks) in PILLAR, or 48 weeks in ASPIRE. A post-hoc analysis evaluated efficacy, adverse events (AEs), and laboratory parameters for TMC435 150 mg only, in F3 and F4 patients. In total, 87 of the 118 F3/F4 patients received TMC435 150 mg QD, while 30 received placebo. Baseline demographics and patient characteristics were similar between trials; the majority were male, white, median age 51-54 years and weight 80-84 kg, 87%-93% had baseline HCV RNA >800,000, and 51% had HCV GT1a.

In PILLAR, the SVR24 rate was 79% overall. 16/19 (84%) F3 patients met RGT criteria, of whom 15 (94%) reached SVR24. In ASPIRE, SVR24 in F3/F4 patients treated with TMC435 was 65% in prior relapsers, 67% in prior partial-responders, and 33% in prior null-responders. Across PILLAR and ASPIRE, similar rates of AEs were observed in F3/F4 patients in TMC435 and control groups, and between F3/F4 patients and study patients overall. Changes in laboratory parameters (including platelets, neutrophils, and hemoglobin) were comparable between TMC435 and control groups, except for mild, reversible bilirubin increases with TMC435.

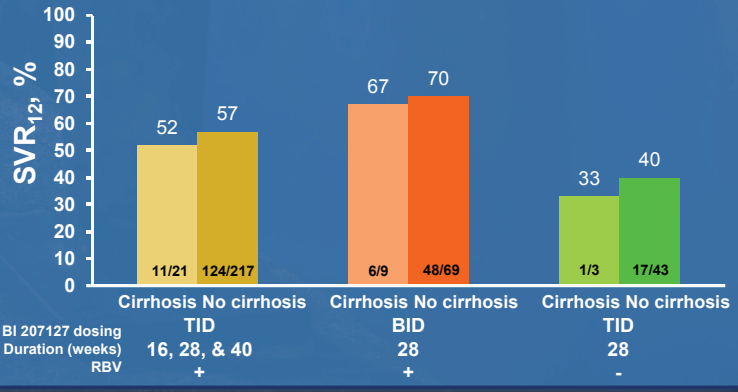
IFN-free Combination of BI 201335 + BI 207127 ± RBV in Treatment-naïve Patients with HCV GT1 Infection and Compensated Liver Cirrhosis: Results from the SOUND-C2 Study

SOUND-C2 was an open-label, randomized study investigating the IFN-free combination of the HCV NS3/4A protease inhibitor BI 201335 (faldaprevir) and the non-nucleoside NS5B inhibitor BI 207127 ± RBV in treatment-naïve patients with HCV GT1 **[Abst. 84]**.[10] The analysis of the overall population demonstrated up to 84% SVR12 in patients with GT1a and IL28B CC or GT1b, while the GT1a non-CC subpopulation had significantly lower SVR12 rates. At AASLD, investigators presented the final SVR12 and safety data from patients with cirrhosis in SOUND-C2.

Thirty three patients with compensated cirrhosis were treated in one of five treatment arms: BI 201335 120 mg QD (1335QD) + BI 207127 600 mg TID (7127TID) + RBV for 16, 28, or 40 weeks (TID + RBV arms); 1335QD + BI 207127 600 mg BID (7127BID) + RBV for 28 weeks (BID arm); and 1335QD + 7127TID (no RBV) for 28 weeks. Results from the TID + RBV arms were pooled since patients received the same regimen and the sample size among cirrhotic patients was small.

Overall, 362 patients were randomized to treatment in the SOUND-C2 trial. Patients with cirrhosis had lower SVR rates across all dose groups compared with those without cirrhosis, although patients with cirrhosis in the BID arm achieved an SVR12 of 67%, compared with 70% in the no cirrhosis group (Figure 4). This is the first study to report data on IFN-free treatment of patients with HCV GT1 infection and compensated liver cirrhosis. The BID dosing of BI 207127 in combination with BI 201335 QD + RBV achieved high SVR rates with good tolerability in patients with cirrhosis.

Figure 4. SVR12: Cirrhosis vs. No Cirrhosis



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MK-5172 + PegIFN + RBV in HCV GT1 Treatment-Naïve Noncirrhotic Patients

MK-5172 is a potent HCV NS3/4A protease inhibitor with a high barrier to resistance. Investigators studied MK-5172 with PegIFN + RBV in HCV GT1 treatment-naive patients and presented safety and efficacy data of a vanguard cohort of patients **[Abst. 766]**.[11]

Patients received either BOC + PegIFN + RBV or MK-5172 100, 200, 400, or 800 mg QD + PegIFN + RBV for 12 weeks, followed by an additional 12 weeks (if RVR was achieved) or 36 weeks (if no RVR) of PegIFN + RBV. The primary end point was the proportion of patients with undetectable HCV RNA at week 12 (MK-5172 arms) or 16 (BOC arm).

The investigators reported that in the vanguard cohort, SVR12 was 96% in the MK-5172 100 mg group, 87% in the MK-5172 200 mg, 87% in the MK-5172 400 mg group, 81% in the MK-5172 800 mg group, and 54% in the BOC group. Overall, it was found that among treatment-naïve, noncirrhotic, HCV G1-infected patients, MK-5172 + PegIFN + RBV had high antiviral potency at all doses; however, the elevated transaminases at higher doses in a subset of patients suggest that doses of 200 mg and less might be preferred in future studies.

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