Program Disclosure

• This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the sponsorship of Purdue University College of Pharmacy and the Chronic Liver Disease Foundation. Purdue College of Pharmacy is accredited by the ACCME to provide continuing medical education for physicians.

• This program is supported by an educational grant from AbbVie and Janssen Pharmaceuticals.
Educational Objectives

• Describe current HCV management recommendations/guidelines

• Understand the treatment regimens likely to be approved in the near/midterm and understand the patient populations for which these regimens are likely to be approved

• Identify the most important baseline characteristics when assessing benefit/risk to treat now or wait
Most Patients with Chronic Hepatitis C in the US Are Not Aware that They Are Infected

- ~3,300,000 individuals are infected with the hepatitis C virus in the United States

Disease Burden of Patients Infected 20 Years or More is Peaking Now

Complications from chronic hepatitis C develop slowly over a period of 20–30 years

- Patients infected
- Infected > 20 y

Davis GL. Rev Gastroenterol Disord 2004;4:7-17.
Deaths from HCV in the United States Continue to Rise; Deaths from HBV and HIV are Decreasing

HCV was the contributing or underlying cause of death for 15,106 individuals in 2007

Deaths from HCV in the United States in 2007 (n=15,106)*
Individuals 45 to 64 Years of Age Most Affected

*Hepatitis C either contributing or underlying cause of death

Changes are Needed in Our HCV Screening and Treatment Practice

Without changes in current identification and treatment practices:

• Total medical costs for patients with HCV infection expected to more than double over the next 20 years

• Deaths are forecasted to increase to 35,000/yr annually by 2030

HCV Prevalence and Disease Burden Highest in the 1945–1965 Birth Cohort

- An estimated 75-80% of persons with chronic hepatitis C were born from 1945 – 1965
- CDC risk-based screening recommendations from 1998 have resulted in low case identification
- In 2012, CDC updated recommendations for one time hepatitis C screening for all baby boomers, regardless of risk factors\(^1\)
- In 2013, U.S. Preventative Services Task Force (USPSTF) recommends\(^2\)
  - Screening in persons at high risk for infection (Grade A)
  - One time screening in persons born between 1945-1965 (Grade B)

Current Therapies
Milestones in Therapy of CHC: Average SVR* Rates from Clinical Trials

*SVR=Sustained Virologic Response; **DAAs=Direct Acting Antivirals

Adapted from US Food and Drug Administration, Antiviral Drugs Advisory Committee Meeting, April 27-28, 2011, Silver Spring MD.
DAAs with an Indication for the Treatment of GT 1 Chronic Hepatitis C

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>boceprevir</td>
<td>Victrelis™</td>
<td>Merck Pharmaceuticals, Inc</td>
</tr>
<tr>
<td>telaprevir</td>
<td>Incivek™</td>
<td>Vertex Pharmaceuticals, Inc</td>
</tr>
</tbody>
</table>

- Both compounds act by inhibiting HCV nonstructural NS3/4A protease and are referred to as direct acting antivirals (DAAs)
Limitations of Current Therapy

- Telaprevir and boceprevir only approved for Genotype 1
- Interferon and ribavirin backbone required
- Twice per day dosing (BID) for telaprevir and three times per day (TID) dosing for boceprevir
- Response guided therapy (both) and lead-in (boceprevir) complicated
- 24-48 week treatment
- Limited efficacy in difficult to cure patients (e.g., patients with cirrhosis, prior null responders, African-Americans)
- Hematologic (both) and rash/dermatological (telaprevir) adverse events
- Drug-drug interactions

Emerging Therapies
Emerging Therapies

• All therapies discussed are currently in clinical development and/or undergoing regulatory review at the FDA.

• Clinical data included highlights the clinical data that has been presented at congresses or published in peer reviewed journals and is not complete.
The Pipeline

- **Protease inhibitors**
  - Simeprevir
  - Faldaprevir
  - Asunaprevir
  - ABT-450
  - MK-5172
  - Sovaprevir
  - ACH-2684

- **NS5A Inhibitors**
  - Daclatasvir
  - Ledipasvir
  - ABT-267
  - GS-5816
  - ACH-3102
  - PPI-668
  - GSK2336805
  - Samatasvir
  - MK-8742
The Pipeline

- NS5B Nuc
  - Sofosbuvir
  - VX-135
  - IDX20963
  - ACH-3422

- NS5B Non-nuc
  - ABT-333
  - Deleobuvir
  - BMS 791325
  - PPI-383
  - GS 9669
  - TMC 647055
Sofosbuvir (SOF) (nuc)
Sofosbuvir (GS-7977)

- NS5B nucleoside polymerase inhibitor
- Favorable administration profile
  - Once daily, no food effect
  - No known drug-drug interactions
Completed Phase 3 Trials

- **NEUTRINO**
  - GT* 1, 4, 5, 6; treatment naive
  - No comparator
- **FISSION**
  - GT 2 and 3; treatment naive
  - Compared to 24 weeks of peginterferon + ribavirin
- **POSITRON**
  - GT 2 and 3; patients ineligible for or intolerant of interferon therapy
  - Compared to placebo
- **FUSION**
  - GT 2 and 3; patients unresponsive to prior treatment
  - Compared to 16 weeks of sofosbuvir + ribavirin

*GT=Genotype
NEUTRINO

- Patients
  - GT 1, 4, 5, 6 treatment naive
  - 17% compensated cirrhosis
  - 17% black
  - 29% IL28B genotype CC

- Regimen for all patients
  - Sofosbuvir 400 mg once daily
  - Ribavirin 1000/1200 mg daily in divided doses
  - Peginterferon alfa-2a 180 mcg weekly
NEUTRINO: Study Design

- **Open label**
  - SOF+PEG+RBV for 12 weeks (no response-guided therapy)
- **Expanded inclusion criteria**
  - No upper limit to age or BMI
  - Opiate replacement therapy permitted
  - Platelets $\geq 90,000/mm^3$, neutrophils $\geq 1,500/mm^3$ or $1,000/mm^3$ (blacks)

NEUTRINO: SVR by Genotype

>90% Of Patients Have Undetectable Virus After 2 Weeks and Achieve SVR

Conclusions

• 12 weeks of SOF+PEG+RBV achieved 90% SVR in treatment naive patients with GT 1, 4, 5, or 6

• 99% of patients had HCV RNA < LLOQ by treatment week 4 and all virologic failures were due to relapse

• This regimen was well tolerated

<\textit{LLOQ}=\textit{Below Lower Limit of Quantitation}

GT2 and GT 3: Study Designs

FISSION (TN)

Week 0 12 24 36
SOF + RBV, n=256
Peg-IFN + RBV (SOC), n=243
SVR12

RBV does 1000-1200 mg/day for SOF + RBV and 800 mg/day for Peg-IFN + RBV.

FUSION (TE)

Week 0 12 16 24 28
SOF + RBV, n=103
Placebo
SOF + RBV, n=98
SVR12

SOF dose 400 mg once daily; RBV dose 1000-1200 mg/day.

POSITRON (Intolerant)

Week 0 12 24
SOF + RBV, n=207
Placebo, n=71
SVR12

SOF dose 400 mg once daily; RBV dose 1000-1200 mg/day.

GT2 and GT 3: SVR by Genotype

**FISSION (TN)**

<table>
<thead>
<tr>
<th></th>
<th>SOF + RBV 12 Weeks</th>
<th>Peg-IFN + RBV 24 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>67/170/253</td>
<td>67/162/243</td>
</tr>
<tr>
<td>GT 2</td>
<td>97/68/70</td>
<td>78/52/67</td>
</tr>
<tr>
<td>GT 3</td>
<td>56/102/183</td>
<td>63/110/176</td>
</tr>
</tbody>
</table>

**FUSION (TE)**

<table>
<thead>
<tr>
<th></th>
<th>SOF + RBV 12 weeks</th>
<th>SOF + RBV 16 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>50/50</td>
<td>73/30</td>
</tr>
<tr>
<td>GT 2</td>
<td>86/31</td>
<td>94/30</td>
</tr>
<tr>
<td>GT 3</td>
<td>30/19</td>
<td>62/39</td>
</tr>
</tbody>
</table>

**POSITRON (Intolerant)**

<table>
<thead>
<tr>
<th></th>
<th>SOF + RBV 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>161/101/109</td>
</tr>
<tr>
<td>GT 2</td>
<td>93/93</td>
</tr>
<tr>
<td>GT 3</td>
<td>61/60</td>
</tr>
</tbody>
</table>

SVR: Patients with Cirrhosis vs. No Cirrhosis

FISSION (TN)

<table>
<thead>
<tr>
<th></th>
<th>No cirrhosis</th>
<th>Cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>GT 2</td>
<td>58/59</td>
<td>59/82</td>
</tr>
<tr>
<td></td>
<td>10/1</td>
<td>11/62</td>
</tr>
<tr>
<td></td>
<td>89/145</td>
<td>99/139</td>
</tr>
<tr>
<td></td>
<td>3/38</td>
<td>11/37</td>
</tr>
</tbody>
</table>

FUSION (TE)

<table>
<thead>
<tr>
<th></th>
<th>No Cirrhosis</th>
<th>Cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>GT 2</td>
<td>25/26</td>
<td>25/23</td>
</tr>
<tr>
<td></td>
<td>6/10</td>
<td>7/9</td>
</tr>
<tr>
<td></td>
<td>14/38</td>
<td>25/40</td>
</tr>
<tr>
<td></td>
<td>5/26</td>
<td>14/23</td>
</tr>
</tbody>
</table>

POSITRON (Intolerant)

<table>
<thead>
<tr>
<th></th>
<th>No cirrhosis</th>
<th>Cirrhosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>GT 2</td>
<td>85/92</td>
<td>16/17</td>
</tr>
<tr>
<td></td>
<td>68/67</td>
<td>21/3</td>
</tr>
</tbody>
</table>

VALENCE: Study Design

*Protocol amended to eliminate placebo arm and to extend treatment duration to 24 weeks for patients with genotype 3 HCV irrespective of prior treatment history.

SVR12 in GT 2 and 3 Patients*

SVR12 in GT 2 Patients Treated for 12 Weeks

*3 of 11 patients (27%) with HCV GT 3 who received 12 weeks of SOF+RBV achieved SVR 12.

SVR12 in GT 3 Patients Treated for 24 Weeks

A Second Strategy for GT 3

LONESTAR-2
Study Design

- Study population
  - HCV GT 2 or 3
  - Failed treatment with pegylated interferon and ribavirin
  - Approximately 50% with compensated cirrhosis
  - HIV and HBV coinfected patients excluded

Lawitz E, et al. Abstract #LB-4, AASLD 2013
Results: SVR12 by HCV Genotype

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>GT 2</th>
<th>GT 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVR12 (%)</td>
<td>42/47</td>
<td>22/23</td>
<td>20/24</td>
</tr>
<tr>
<td></td>
<td>89</td>
<td>96</td>
<td>83</td>
</tr>
</tbody>
</table>

Lawitz E, et al. Abstract #LB-4, AASLD 2013
Results: SVR12 by Cirrhosis Status

- **SVR12 (%)**
  - **GT 2**
    - No Cirrhosis: 100
    - Cirrhosis: 93
    - 9/9 vs. 13/14
  - **GT 3**
    - No Cirrhosis: 83
    - Cirrhosis: 83
    - 10/12 vs. 10/12

Error bars represent 95% confidence intervals.

Lawitz E, et al. Abstract #LB-4, AASLD 2013
## Results: Adverse Events

<table>
<thead>
<tr>
<th>Overall safety</th>
<th>SOF + PEG/RBV 12 weeks (N=47)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>AEs</td>
<td>45 (96)</td>
</tr>
<tr>
<td>Grade 3-4 AEs</td>
<td>15 (32)</td>
</tr>
<tr>
<td>Serious AEs</td>
<td>4 (9)</td>
</tr>
<tr>
<td>Treatment discontinuation due to AEs</td>
<td>2 (4)</td>
</tr>
</tbody>
</table>

| Hematologic abnormalities |                                |
|---------------------------|                                |
| Grade 3-4 laboratory abnormality | 28 (60)                    |
| Hemoglobin <10 g/dL       | 13 (28)                        |
| Hemoglobin <8.5 g/dL      | 4 (9)                          |
| Absolute neutrophil count <750/mm³ | 13 (28)                  |
| Platelets <50,000/mm³     | 7 (15)                         |

Lawitz E, et al. Abstract #LB-4, AASLD 2013
Conclusions

• 12 weeks of SOF+RBV results in SVR>90% in GT* 2 treatment naive patients with and without cirrhosis
• SVR rates were lower in GT 2 treatment experienced patients with cirrhosis compared to non-cirrhosis
• SOF+RBV led to similar results as PEG+RBV for GT 3 treatment naïve patients
  – Lowest rates observed in patients with cirrhosis
• SOF+RBV for 12 weeks is suboptimal for GT 3 treatment experienced patients
  – 24 weeks total duration significantly increased SVR rates
  – In GT 3 PEG+RBV+SOF for 12 weeks may maximize outcomes.
• GT 3 ≠ GT 2 HCV
  – Strategies to improve GT 3 results are needed

*GT=Genotype
Simeprevir (SMV) (PI)
Simeprevir (TMC 435)

- NS3/4A protease inhibitor
- Antiviral activity against GT 1, 2, 4, 5 and 6
- One capsule, once per day
Completed Phase 3 Studies

- QUEST-1 and QUEST-2
  - Same study design but studies conducted independent of one another
  - Treatment naive GT 1 patients

- PROMISE
  - Same study design as QUEST-1 and QUEST-2
  - GT 1 prior relapsers
Response Guided Therapy: if HCV RNA <25 International Units/mL at Week 4 and undetectable at Week 12, complete treatment at Week 24

- 85-93% of patients met the criteria and qualified for total treatment duration of 24 weeks.

*PEG/RBV=Peginterferon/Ribavirin;
Simeprevir + PEG/RBV Achieved SVR in ~80% of Treatment Naive and Prior Relapsers
I. Jacobson et al, Abstract 1425. EASL, April 2013
SVR Higher When Simeprevir Added to PEG/RBV For Patients With All Stages of Fibrosis/Cirrhosis (QUEST-2)

Similar results seen in QUEST-1 and PROMISE studies
Conclusions

• Simeprevir 150 mg + PEG/RBV was highly effective against GT 1 treatment naive patients with SVR (80%)

• Most patients (85%) receiving simeprevir were able to shorten therapy to 24 weeks

• Simeprevir 150 mg + PEG/RBV was generally well tolerated
  – Rates of anemia and rash were similar in the simeprevir and placebo groups
Simeprevir (TMC 435) (PI) + Sofosbuvir (GS-7977) (nuc)
Background

- Simeprevir (TMC435) is an investigational, one pill, once-daily, potent oral HCV NS3/4A protease inhibitor recently approved in Japan and currently under regulatory review in North America and Europe.

- Sofosbuvir (GS-7977) is an HCV nucleotide NS5B polymerase inhibitor also currently under regulatory review.

- COSMOS is a Phase IIa, randomized, open-label study investigating simeprevir + sofosbuvir +/- ribavirin.

- Interim analysis.
COSMOS: Study design

- Cohort 1: Prior null responders (METAVIR F0-F2)
  - Final SVR12 for all arms
- Cohort 2: Treatment-naïve and prior null responders (METAVIR F3-F4)
  - Interim SVR4 for Arms 3 and 4

Enrollment ratio 2:1:2:1

N=14  Arm 1  SMV + SOF + RBV  Post-treatment follow-up

N=24  Arm 2  SMV + SOF  Post-treatment follow-up

N=14  Arm 3  SMV + SOF + RBV  Post-treatment follow-up

N=27  Arm 4  SMV + SOF  Post-treatment follow-up

Cohort 1: Null responders (F0-2)

24 week treatment

- SMV/SOF 24 wks: 1/15 (6.7%), 14/15 (93.3%)
- SMV/SOF/RBV 24 wks: 4/24 (16.7%), 19/24 (79%)  

12 week treatment

- SMV/SOF 12 wks: 1/14 (7.1%), 13/14 (92%)  
- SMV/SOF/RBV 12 wks: 3.7%, 26/27 (96%)

Legend:
- Red: SVR12 (SMV/SOF)
- Orange: Non-virologic failure
- Blue: SVR12 (SMV/SOF/RBV)
- Green: Relapse

Cohort 2: Naïve and prior null responders (F3-4): Interim analysis, SVR4

12 week treatment

<table>
<thead>
<tr>
<th></th>
<th>SVR4 (SMV/SOF)</th>
<th>SVR4 (SMV/SOF/RBV)</th>
<th>Relapse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
<td>1/27</td>
</tr>
<tr>
<td>Naïves</td>
<td>100</td>
<td>100</td>
<td>26/27</td>
</tr>
<tr>
<td>Nulls</td>
<td>100</td>
<td>93.3</td>
<td>6.7/15</td>
</tr>
</tbody>
</table>

### Most Common AEs: Cohorts 1 and 2 Combined

<table>
<thead>
<tr>
<th>Patients, n (%)</th>
<th>24 weeks</th>
<th>12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SMV + SOF + RBV (n=54)</td>
<td>SMV + SOF (n=31)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>20 (37.0)</td>
<td>10 (32.3)</td>
</tr>
<tr>
<td>Headache</td>
<td>11 (20.4)</td>
<td>7 (22.6)</td>
</tr>
<tr>
<td>Nausea</td>
<td>6 (11.1)</td>
<td>4 (12.9)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>9 (16.7)</td>
<td>2 (6.5)</td>
</tr>
<tr>
<td>Rash</td>
<td>7 (13.0)</td>
<td>3 (9.7)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>9 (16.7)</td>
<td>1 (3.2)</td>
</tr>
<tr>
<td>Photosensitivity/sunburn&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2 (3.7)</td>
<td>1 (3.2)</td>
</tr>
<tr>
<td>Anemia</td>
<td>11 (20.4)</td>
<td>1 (3.2)</td>
</tr>
</tbody>
</table>

<sup>a</sup>No sun-protective measures were in place for this trial.

RBV, ribavirin; SMV, simeprevir; SOF, sofosbuvir

Conclusion

• Treatment with SMV + SOF ± RBV results in:
  – High SVR12 rates in HCV GT 1 null responder patients
  – High SVR4 rates in naïve and null-responder patients with METAVIR F3-F4

• Addition of RBV to SMV + SOF may not be needed to achieve high rates of SVR in this patient population

• 12 weeks of treatment may confer similar SVR rates compared with 24 weeks of treatment

• SMV + SOF ± RBV was generally well tolerated
ABT-450/r (PI with ritonavir), ABT-267 (NS5A inhibitor) and ABT-333 (non nuc)
AVIATOR

• Phase 2b, randomized, open-label, multicenter study

• Patients
  – GT 1 (66% GT 1a)
  – Treatment-naive and prior null response
  – Non-cirrhotic

• Duration
  – 8, 12 and 24 weeks

K.V. Kowdley et al, Abstract 3. EASL, April 2013
AVIATOR: Study Design

** 8 patients who achieved SVR12 did not return >24 weeks and were counted as virological failures for SVR24
3 patients relapsed between SVR12 and SVR24

K.V. Kowdley et al, Abstract 3. EASL, April 2013
SVR\textsubscript{24} by Baseline Subgroups – Treatment-Naive Patients*

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
<th>1a</th>
<th>1b</th>
<th>≥7 log</th>
<th>&lt;7 log</th>
<th>F0-F1</th>
<th>F2-F3</th>
<th>Non-CC</th>
<th>CC</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=</td>
<td>78</td>
<td>81</td>
<td>108</td>
<td>50</td>
<td>35</td>
<td>124</td>
<td>113</td>
<td>42</td>
<td>115</td>
<td>44</td>
</tr>
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<td></td>
<td>92</td>
<td>94</td>
<td>91</td>
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<td>89</td>
<td>94</td>
<td>94</td>
<td>91</td>
<td>95</td>
<td>89</td>
</tr>
</tbody>
</table>

*Includes patients randomized to the quad therapy arms (12 or 24 weeks duration).

K.V. Kowdley et al, Abstract 3. EASL, April 2013
SVR$_{24}$ by Baseline Subgroups – Null Responders*

*Includes patients randomized to the quad therapy arms (12 or 24 weeks duration).

K.V. Kowdley et al, Abstract 3. EASL, April 2013
# Most Common Adverse Events*

<table>
<thead>
<tr>
<th>Event, %</th>
<th>Total (N=247)</th>
<th>Treatment-Naïve (N=159)</th>
<th>Null Responders (N=88)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>31.2</td>
<td>31.4</td>
<td>30.7</td>
</tr>
<tr>
<td>Fatigue</td>
<td>29.6</td>
<td>32.7</td>
<td>23.9</td>
</tr>
<tr>
<td>Nausea</td>
<td>22.7</td>
<td>24.5</td>
<td>19.3</td>
</tr>
<tr>
<td>Insomnia</td>
<td>19.8</td>
<td>22.6</td>
<td>14.8</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>15.0</td>
<td>13.2</td>
<td>18.2</td>
</tr>
</tbody>
</table>

*Includes patients randomized to the quad therapy arms (12 or 24 weeks duration)

K.V. Kowdley et al, Abstract 3. EASL, April 2013
Safety

• 6 patients (2.4%) discontinued due to study drug-related AEs; 4 of 6 considered related to treatment.

• 4 patients (1.6%) experienced SAEs
  – 1 (arthralgia) was possibly study drug-related

• Moderate-to-severe study drug-related AEs with >10% incidence in any arm were asthenia and fatigue.

• 6 patients (2.8%) and 1 patient (0.6%) experienced Grade 3-4 laboratory abnormalities in total bilirubin and ALT, respectively; all resolved with continued dosing.

K.V. Kowdley et al, Abstract 3. EASL, April 2013
AVIATOR Conclusions

- Comparable SVR12 and 24 seen with 12 and 24 weeks of treatment
- SVR rates >90% were achieved in naive and prior null responders with a 3-DAA+RBV regimen
  - No clinically meaningful differences were observed by gender, HCV subtype, IL28B genotype, baseline HCV-RNA or severity of fibrosis.

K.V. Kowdley et al, Abstract 3. EASL, April 2013
Daclatasvir (DCV) (NS5A inhibitor) + Sofosbuvir (SOF) (GS-7977) (nuc)
Background

• Patients who experience virologic failure on telaprevir or boceprevir-based regimens currently have no treatment options

• Daclatasvir (DCV) plus SOF with or without RBV achieved SVR4 in 98% of 126 HCV GT 1-infected treatment-naive patients (Sulkowski et al. AASLD 2012)

• Study Aim
  
  – To evaluate the efficacy and safety of DCV+SOF with or without RBV for 24 weeks in GT 1-infected patients who failed prior treatment with TVR or BOC + PEG/RBV

M.S. Sulkowski et al, Abstract 1417. EASL, April 2013
Study Design

**Patients**

- GT 1, non-cirrhotic
- Prior nonresponse, relapse, or breakthrough during treatment with PEG/RBV+TVR or BOC
- Patients who discontinued TVR or BOC due to an adverse event were excluded

M.S. Sulkowski et al, Abstract 1417. EASL, April 2013
Virologic Response

- 1 patient missing at follow up week 12: HCV RNA was undetectable at follow up week 4 and follow up week 24
- 21/41 patients have reached follow up week 24; all have achieved SVR24

M.S. Sulkowski et al, Abstract 1417. EASL, April 2013
Conclusions

• The all-oral, once-daily combination of DCV+SOF with or without RBV achieved SVR24 in all GT 1 infected patients who failed prior treatment with TVR or BOC+PEG/RBV

• DCV+SOF with or without RBV was well tolerated

• No Grade 3 or 4 hepatic or hematologic abnormalities