HCV: Highlights
From EASL 2013
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HCV: Highlights From EASL 2013

- Current treatments
- Upcoming treatments
- Future regimens
SVR12 Rates and Safety of Triple Therapy Including Telaprevir or Boceprevir in 221 Cirrhotic Non Responders Treated in The French Early Access Program (ANRS CO20-CUPIC)


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CUPIC: French early access program

- EASL 2012 report: increased SAEs and deaths
- Design: cohort study
  - Selection of boceprevir or telaprevir made by the clinician
- Patients
  - Genotype 1
  - Patients with compensated cirrhosis
    - Approximately 1/3 would not have qualified for phase 3 trials
  - Prior relapse and partial response
- Regimens
  - Standard protocols for boceprevir (lead-in) and telaprevir
  - 48 weeks for all patients

H. Fontaine et al, Abstract 60. EASL, April 2013
CUPIC SVR12 Results

H. Fontaine et al, Abstract 60. EASL, April 2013
CUPIC: French early access program

- Predictors of response
  - Prior relapse > prior partial/null response
  - Genotype 1b > 1a

H. Fontaine et al, Abstract 60. EASL, April 2013
## CUPIC: Safety Findings

<table>
<thead>
<tr>
<th>Event</th>
<th>Telaprevir n=295</th>
<th>Boceprevir n=190</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients, n</strong> (% patients with at least one event)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious adverse events (SAEs)</td>
<td>535 in 160 patients (54.2%)</td>
<td>321 in 97 patients (51.0%)</td>
</tr>
<tr>
<td>Premature discontinuation / Due to SAEs</td>
<td>139 (47.1%) / 63 (21.3%)</td>
<td>80 (42.1%) / 27 (14.2%)</td>
</tr>
<tr>
<td>Death</td>
<td>7 (2.4%)</td>
<td>3 (1.6%)</td>
</tr>
<tr>
<td>Infection (Grade 3/4)</td>
<td>27 (9.1%)</td>
<td>8 (4.2%)</td>
</tr>
<tr>
<td>Hepatic decompensation (Grade 3/4)</td>
<td>15 (5.1%)</td>
<td>9 (4.7%)</td>
</tr>
<tr>
<td>Anemia (Grade 3/4: Hb &lt; 8 g/dL)</td>
<td>38 (12.9%)</td>
<td>19 (10%)</td>
</tr>
<tr>
<td>Rash (Grade 3/SCAR)</td>
<td>16 (5.4%) / 2 (0.6%)</td>
<td>2 (1.0%) / 0</td>
</tr>
<tr>
<td>EPO use / Blood transfusion</td>
<td>168 (57%) / 53 (18%)</td>
<td>119 (62.6%) / 26 (13.7%)</td>
</tr>
<tr>
<td>GCSF use</td>
<td>8 (2.7%)</td>
<td>13 (6.8%)</td>
</tr>
<tr>
<td>TPO use</td>
<td>6 (2%)</td>
<td>3 (1.6%)</td>
</tr>
</tbody>
</table>

SCAR: severe cutaneous adverse reaction

Fontaine H, et al. 48th EASL; Amsterdam, Netherlands; April 24-28, 2013. Abstract 60
CUPIC: French early access program

- Large “real life” cohort of patients with cirrhosis
- SVR$_{12}$ rate comparable to subgroup of patients with severe fibrosis or cirrhosis of phase III studies
- Increased risk of serious adverse events, particularly severe infections and anemia

H. Fontaine et al, Abstract 60. EASL, April 2013
Safety of Triple Therapy With Telaprevir or Boceprevir in Hepatitis C Patients With Advanced Liver Disease - Predictive Factors For Sepsis

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Predictive factors for sepsis

- 110 genotype 1 patients
- Boceprevir or telaprevir regimen x 48 weeks
- Serious adverse events: 22 (20%)
  - Severe infections: 11
- Predictors of severe infection
  - Platelet count < 100,000/L: 13.4% vs. 8.7%, P < 0.05
  - Serum albumin < 3.5g/dL: 55.6% vs. 5.4%, P < 0.05
  - Hepatovenous pressure gradient (HVPG) measurement
    - available in 27 patients with cirrhosis
    - HVPG ≥ 10 mm Hg: 6/18 infections
    - HPVG < 10 mm Hg: 0/9 infections

K. Rutter et al, Abstract 65. EASL, April 2013
High SVR Rates (SVR4) For 12-week Total Telaprevir Combination Therapy In IL28b CC Treatment-Naïves And Prior Relapsers With G1 Chronic Hepatitis C: CONCISE Interim Analysis

D.R. Nelson1*, F. Poordad2, J.J. Feld3, M.W. Fried4, I.M. Jacobson5, P.J. Pockros6, M.S. Sulkowski7, S. Zeuzem8, L. Bengtsson9, S. George9, M.I. Friedman9, on behalf of the CONCISE Study Team

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CONCISE

– Patients
  • IL28B CC (favorable genotype)
  • Treatment-naïve or prior relapse
  • No cirrhosis

– Treatment
  • Peginterferon alfa-2a 180 mcg subcu weekly
  • Ribavirin 1000/1200 mg daily
  • Telaprevir 1125 mg bid

– Regimen
  • Patients with RVR were randomized 2:1 at week 12
    – T12/PR12
    – T12/PR24

D.R. Nelson et al, Abstract 818. EASL, April 2013
CONCISE Interim SVR12

D.R. Nelson et al, Abstract 818. EASL, April 2013
CONCISE

– Conclusion

• High SVR rates from the CONCISE study interim analysis suggest the potential for the defined IL28B CC patients with RVR to shorten duration of telaprevir plus peginterferon/ribavirin to 12 weeks
HCV: Highlights From EASL 2013

- Current treatments
- Upcoming treatments
- Future regimens
Phase 3 Randomized Controlled Trial Of All-Oral Treatment With Sofosbuvir+Ribavirin For 12 Weeks Compared To 24 Weeks Of PEG+Ribavirin In Treatment-Naïve GT2/3 HCV-Infected Patients (FISSION)

E. Gane¹*, E. Lawitz², M. Rodriguez-Torres³, S. Gordon⁴, H. Dvory-Sobol⁵, S. Arterburn⁵, J. McNally⁵, D.M. Brainard⁵, W.T. Symonds⁵, J.G. McHutchison⁵, A. Sheikh⁶, A. Mangia⁷

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FISSION

– Phase 3 study
– Sofosbuvir (GS-7977): nucleoside polymerase inhibitor
  • Favorable administration profile
    – Once daily, no food effect
    – No drug-drug interactions
– Patients
  • Genotype 2/3 treatment naive
  • 20% cirrhosis
– Regimen
  • Sofosbuvir 400 mg qd + ribavirin 1000/1200 mg for 12 weeks
  • Peginterferon alfa-2a 180 mcg + ribavirin 800 mg for 24 weeks

FISSION: SVR12 by genotype

FISSION: SVR12 by genotype and cirrhosis/no cirrhosis

FISSION

– Sequencing
  • 79 SOF + RBV patients who did not achieve SVR12
  • No resistance associated variants (S282T)

– Safety summary

<table>
<thead>
<tr>
<th></th>
<th>SOF + RBV</th>
<th>PEG + RBV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 3-4 Adverse events</td>
<td>7%</td>
<td>19%</td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>D/C due to adverse events</td>
<td>1%</td>
<td>11%</td>
</tr>
<tr>
<td>Hemoglobin &lt;10 gm/dL</td>
<td>9%</td>
<td>15%</td>
</tr>
<tr>
<td>Neutrophils &lt;750/mm³</td>
<td>0%</td>
<td>15%</td>
</tr>
<tr>
<td>Platelets &lt;50,000/mm³</td>
<td>0%</td>
<td>7%</td>
</tr>
</tbody>
</table>

FISSION

Conclusions

- SOF + RBV (12 weeks) led to excellent results (SVR12 > 90%) in genotype 2 patients with and without cirrhosis
- SOF + RBV (12 weeks) led to similar results as PEG + RBV (24 weeks) for genotype 3 patients
  - Lowest rates observed in patients with cirrhosis
  - Strategies to improve genotype 3 results are needed
- SOF + RBV well tolerated with fewer adverse events than PEG + RBV

Sofosbuvir + Peginterferon + Ribavirin For 12 Weeks Achieves 90% SVR12 In Genotype 1, 4, 5, Or 6 HCV Infected Patients: The NEUTRINO Study

E. Lawitz\textsuperscript{1}, D. Wyles\textsuperscript{2}, M. Davis\textsuperscript{3}, M. Rodriguez-Torres\textsuperscript{4}, K.R. Reddy\textsuperscript{5}, K.V. Kowdley\textsuperscript{6}, E. Svarovskaia\textsuperscript{7}, D. Jiang\textsuperscript{7}, J. McNally\textsuperscript{7}, D.M. Brainard\textsuperscript{7}, W.T. Symonds\textsuperscript{7}, J.G. McHutchison\textsuperscript{7}, L. Nyberg\textsuperscript{8}, Z. Younossi\textsuperscript{9}

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NEUTRINO

– Sofosbuvir (GS-7977)

– Patients
  • Genotypes 1, 4, 5, 6 treatment naive
  • 17% compensated cirrhosis
  • 17% black
  • 29% IL28B genotype CC

– Regimen for all patients
  • Sofosbuvir 400 mg qd
  • Ribavirin 1000/1200 mg
  • Peginterferon alfa-2a 180 mcg weekly

– Duration: 12 weeks

NEUTRINO: SVR12 by genotype

NEUTRINO: SVR12 rates by subgroups

Conclusions

- 12 weeks of treatment with SOF + PEG-IFN + RBV achieved 90% SVR12 in treatment naïve patients with HCV genotype 1, 4, 5, or 6

- 99% of patients had HCV RNA < LLOQ by treatment week 4 and relapse accounted for all virologic failures

- This regimen was well tolerated

Simeprevir (TMC435) with peginterferon/ribavirin for chronic HCV genotype-1 infection in treatment naïve patients: results from QUEST-1, a phase III trial

I. Jacobson¹*, G.J. Dore², G.R. Foster³, M.W. Fried⁴, M. Radu⁵, V.V. Rafalskiy⁶, L. Moroz⁷, A. Craxì⁸, M. Peeters⁹, O. Lenz⁹, S. Ouwerkerk-Mahadevan¹⁰, R. Kalmeijer¹¹, M. Beumont-Mauviel⁹

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I. Jacobson et al, Abstract 1425. EASL, April 2013
QUEST-1

- Simeprevir: potent, once-daily, oral HCV NS3/4A protease inhibitor
- Phase III, randomized, double-blind, placebo-controlled trial
- Patients
  - Treatment naïve genotype 1 infection
- Regimen
  - PEG + RBV + simeprevir 150 mg qd
  - PEG + RBV + placebo
- Algorithm
  - Simeprevir for first 12 weeks
  - Response guided therapy
    - RVR: PEG/RBV x 24 weeks
    - No RVR: PEG/RBV x 48 weeks

I. Jacobson et al, Abstract 1425. EASL, April 2013
QUEST-1: SVR12 rates

I. Jacobson et al, Abstract 1425. EASL, April 2013
QUEST-1: SVR12 rates in subgroups

I. Jacobson et al, Abstract 1425. EASL, April 2013
QUEST-1 Conclusions

- Simeprevir 150 mg + PEG/RBV was highly effective against HCV genotype 1 treatment naïve patients with SVR12 (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

I. Jacobson et al, Abstract 1425. EASL, April 2013
Faldaprevir Plus Pegylated Interferon Alfa-2a and Ribavirin In Chronic HCV Genotype-1 Treatment-Naïve Patients: Final Results From STARTVerso1, A Randomised, Double-blind, Placebo-controlled Phase III Trial


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Faldaprevir (FDV) is a once-daily NS3/4A protease inhibitor

Phase III, randomized, double-blind, placebo-controlled trial

Patients
- Treatment naïve genotype 1 infection
- 78% Caucasian, 20% Asian
- 39% IL28B CC
- 66% genotype 1b

Regimen
- PEG + RBV for 24 weeks plus
  - Placebo for 24 weeks
  - Faldaprevir 120 mg qd
  - Faldaprevir 240 mg qd
- Patients with early treatment success (ETS, HCV RNA < 25IU/mL at Week 4 and undetectable at Week 8) in Arms 2 and 3 stopped all treatment at Week 24
- Patients without ETS and those in Arm 1 received PegIFN/RBV for 48 weeks.

P. Ferenci et al, Abstract 1416. EASL, April 2013
STARTVerso1 SVR12 rates

P. Ferenci et al, Abstract 1416. EASL, April 2013
Conclusions

- FDV plus PegIFN/RBV significantly increased SVR12 rates in HCV GT-1 patients in Europe and Japan compared with PegIFN/RBV
- In total, 88% of patients treated with FDV were eligible to stop all treatment at Week 24
- FDV plus PegIFN/RBV was well tolerated

P. Ferenci et al, Abstract 1416. EASL, April 2013
HCV: Highlights From EASL 2013

– Current treatments
– Upcoming treatments
– Future regimens
Safety and Efficacy of Interferon-free Regimens of ABT-450/R, ABT-267, ABT-333 +/- Ribavirin In Patients With Chronic HCV GT1 Infection: Results From The AVIATOR Study


Digestive Disease Institute, Virginia Mason Medical Center, Seattle, WA, ²University of Texas Health Science Center, San Antonio, TX, ³Abbott Laboratories, Abbott Park, IL, ⁴University of Florida College of Medicine, Gainesville, FL, USA, ⁵J.W. Goethe University, Frankfurt, Germany, ⁶University of Colorado Denver, Aurora, CO, ⁷Indiana University, Indianapolis, IN, USA, ⁸Queen Mary’s University of London, Barts Health, London, UK, ⁹Johns Hopkins University, Baltimore, MD, USA.

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AVIATOR

- Phase 2, randomized, open-label, multicenter study
- Patients
  - Genotype 1 (66% genotype 1a)
  - Treatment-naïve and prior null response
  - Non-cirrhotic
- Medications
  - ABT-450/r (HCV protease inhibitor boosted with ritonavir 100 mg)
  - ABT-267 (NS5A inhibitor)
  - ABT-333 (non-nucleoside NS5B inhibitor)
  - Ribavirin
- Duration
  - 8, 12 and 24 weeks

K.V. Kowdley et al, Abstract 3. EASL, April 2013
### SVR12 (％)
<table>
<thead>
<tr>
<th>N</th>
<th>Regimen/duration</th>
<th>SVR12 (%)</th>
<th>SVR24 (%)</th>
<th>VBT/Relapse</th>
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<tbody>
<tr>
<td>80</td>
<td>ABT450 ABT267 ABT333 RBV</td>
<td>89</td>
<td>88</td>
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<tr>
<td>41</td>
<td>ABT450 ABT333 RBV</td>
<td>85</td>
<td>83</td>
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<td>79</td>
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<td>91</td>
<td>89</td>
<td>1/8</td>
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<tr>
<td>79</td>
<td>ABT450 ABT267 ABT333</td>
<td>90</td>
<td>87</td>
<td>1/5</td>
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<tr>
<td>79</td>
<td>ABT450 ABT267 ABT333 RBV</td>
<td>99</td>
<td>96</td>
<td>0/1</td>
</tr>
<tr>
<td>80</td>
<td>ABT450 ABT267 ABT333 RBV</td>
<td>93</td>
<td>90</td>
<td>0/2</td>
</tr>
</tbody>
</table>

Week | 8 | 12 | 24 |
---|---|---|---
**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
AVIATOR Conclusions

– Comparable SVR12 and 24 seen with 12 and 24 weeks of treatment
  • Selection of a 12-week duration of therapy in these populations

– SVR rates >90% were achieved in naïve and prior null responder patients with a 3-DAA+RBV regimen
  • No clinically meaningful differences were observed by sex, HCV subtype, IL28B genotype, baseline HCV-RNA or severity of fibrosis.

K.V. Kowdley et al, Abstract 3. EASL, April 2013
Sustained Virologic Response With Daclatasvir Plus Sofosbuvir ± Ribavirin (RBV) In Chronic HCV Genotype (Gt) 1-infected Patients Who Previously Failed Telaprevir (TVR) or Boceprevir (BOC)


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Background

- Patients who experience virologic failure on telaprevir or boceprevir-based regimens currently have no treatment options
- Daclatasvir (DCV): NS5A inhibitor
- Sofosbuvir (SOF): nucleotide NS5B polymerase inhibitor
- 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)

Aim:

- To evaluate the efficacy and safety of DCV plus SOF with or without RBV for 24 weeks in HCV GT 1-infected patients who failed prior treatment with TVR or BOC + pegIFN-alfa/RBV

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

Prior TVR/BOC failures, GT 1a/1b (N = 41)

- Patients
  - Genotype 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: DCV + SOF in TVR or BOC/PR failures (mITT)

*1 patient missing at post-treatment (PT) Week 12: HCV RNA was undetectable at PT Week 4 and at PT Week 24 21/41 patients have reached PT Week 24; all have achieved SVR24

Sulkowski M, et al. 48th EASL; Amsterdam, Netherlands; April 24-28, 2013. Abstract 1417.
Conclusion

– The all-oral, once-daily combination of DCV + SOF with or without RBV achieved SVR in all HCV GT 1-infected patients (n=41) who failed prior treatment with TVR or BOC + pegIFN-alfa/RBV

– DCV + SOF with or without RBV was well tolerated
  • No grade 3 or 4 hepatic or hematologic abnormalities

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