3D (Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir) + RBV in GT1

TURQUOISE-I

3D + Ribavirin for HCV-HIV Coinfection and GT1
TURQUOISE-I: Part 1a Study Design

TURQUOISE-I: Features

- **Design**: Multipart, phase 2/3, randomized, open-label trial evaluating safety and efficacy of 3D (ombitasvir-paritaprevir-ritonavir and dasabuvir) plus ribavirin for 12 or 24 weeks in treatment-naïve and experienced patients with chronic HCV GT 1 and HIV coinfection, including patients with cirrhosis

- **Setting**: Multicenter study in United States and Puerto Rico

- **Entry Criteria**
  - Chronic HCV infection with genotype 1 and HIV coinfection
  - Treatment-naïve or previously treated with peginterferon + ribavirin
  - Age 18-70
  - Plasma HCV RNA greater than 10,000 IU/mL
  - Child-Pugh A cirrhosis permitted
  - CD4 count $\geq$200 cells/mm$^3$ (or CD4% $\geq$14) and HIV RNA level <40 copies/ml
  - Receiving atazanavir- or raltegravir-based regimen

- **Primary End-Point**: SVR12

3D + Ribavirin for HCV-HIV Coinfection and GT1

TURQUOISE-I: Part 1a Study Regimens

N = 31
3D + Ribavirin

N = 32
3D + Ribavirin

3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir

Drug Dosing
Ombitasvir-Paritaprevir-Ritonavir (25/150/100 mg once daily) and Dasabuvir: 250 mg twice daily
Ribavirin (RBV): weight-based and divided bid (1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg)

### 3D + Ribavirin for HCV-HIV Coinfection and GT 1
#### TURQUOISE-I: Patient Population

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>12-Week Arm (n=31)</th>
<th>24-Week Arm (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), Mean</td>
<td>50.9</td>
<td>50.9</td>
</tr>
<tr>
<td>Male sex %</td>
<td>94</td>
<td>91</td>
</tr>
<tr>
<td>Black Race (%)</td>
<td>23</td>
<td>25</td>
</tr>
<tr>
<td>Cirrhosis (%)</td>
<td>19</td>
<td>19</td>
</tr>
<tr>
<td>HCV genotype (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a</td>
<td>87</td>
<td>91</td>
</tr>
<tr>
<td>1b</td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td>HCV RNA, log_{10} IU/ml (mean)</td>
<td>6.54</td>
<td>6.60</td>
</tr>
<tr>
<td>IL28B non-CC genotype, (%)</td>
<td>84</td>
<td>78</td>
</tr>
<tr>
<td>Previous Response to PEG + RBV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naïve</td>
<td>65</td>
<td>69</td>
</tr>
<tr>
<td>Relapse</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Partial response</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>Null response</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>CD4 Count, cells/mm³ (mean)</td>
<td>633</td>
<td>625</td>
</tr>
</tbody>
</table>

3D + Ribavirin for HCV-HIV Coinfection and GT 1
TURQUOISE-I: Part 1a Results

TURQUOISE-I: SVR Rates (to date)

<table>
<thead>
<tr>
<th></th>
<th>SVR4</th>
<th>SVR12</th>
</tr>
</thead>
<tbody>
<tr>
<td>3D + RBV x 12 Weeks</td>
<td>29/31 (93.5%)</td>
<td>30/32 (93.8%)</td>
</tr>
<tr>
<td>3D + RBV x 24 Weeks</td>
<td>29/31 (93.5%)</td>
<td>29/32 (90.6%)</td>
</tr>
</tbody>
</table>

3D = Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir; RBV = Ribavirin

Details of Five Patients NOT Achieving SVR 12

- One patient in 12-week arm withdrew consent prior to finishing treatment; had undetectable HCV RNA at week 10

- One patient in 12-week arm had virologic relapse at week 4 post treatment; had new resistant HCV variants at 3 viral targets (D168V in NS3/4A, M28T in NS5A, and S556G in NS5B)

- One patient in 24-week arm had virologic breakthrough during treatment; had new resistant HCV variants at 3 viral targets (R155K in NS3/4A, Q30R in NS5A, and S556G in NS5B)

- Two patients in 24-week arm achieved early SVR but appeared to be reinfected with GT1a isolate distinct from baseline HCV isolate; both patients had engaged in high-risk sexual activity post treatment

Conclusions and Relevance: “In this open-label, randomized uncontrolled study, treatment with the all-oral, interferon-free 3D-plus-ribavirin regimen resulted in high SVR rates among patients co-infected with HCV genotype 1 and HIV-1 whether treated for 12 or 24 weeks. Further phase 3 studies of this regimen are warranted in patients with co-infection.”
This slide deck is from the University of Washington’s *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online

[www.hepatitisc.uw.edu](http://www.hepatitisc.uw.edu)

Hepatitis Web Study


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