Asian and White Patients With Chronic Hepatitis C (CHC) Achieve Similar Response Rates With Peginterferon (PEG-IFN) Alfa-2b Plus Ribavirin (RBV) in Genotypes (G) 2 and 3: Subanalysis of the REDD 2/3 Study

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Abstract

Efficacy Assessments
- The primary efficacy endpoint was the proportion of patients achieving SVR, defined as undetectable HCV RNA 24 weeks after the end of treatment.
- An intention-to-treat analysis was performed, with treatment cessation for any reason considered to be failure.
- Patients who withdrew from treatment prematurely were analyzed as failures.
- SVR was defined as achieving undetectable HCV RNA 24 weeks after the end of treatment (end of treatment plus 24 weeks).

Background
- The main aim of the REDD 2/3 study was to evaluate the efficacy and safety of PEG-IFN alfa-2b plus RBV in Asian and white patients with CHC G2 or G3 infection.
- The study was conducted in India, Indonesia, Israel, Malaysia, Poland, Singapore, and Thailand.

Aim
- The aim of this study was to assess the efficacy and safety of PEG-IFN alfa-2b plus RBV in Asian and white patients with CHC G2 or G3 infection.

Methods

Patients
- Patients with CHC G2 or G3 infection
- On-treatment analysis
- An open-label, multicenter, randomized, parallel-group study
- Baseline characteristics
- SVR rates were similar between Asian and white patients within treatment arms

Results

Patient Characteristics

Baseline HCV RNA, n (%)

Table 1: Baseline Demographics in the International Cohort

<table>
<thead>
<tr>
<th></th>
<th>Asian (n = 52)</th>
<th>White (n = 56)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV genotype 3</td>
<td>18 (50.0)</td>
<td>18 (50.0)</td>
<td>1.00</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>39.7 (10.4)</td>
<td>39.4 (11.0)</td>
<td>0.11</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>21 (40.4)</td>
<td>23 (41.1)</td>
<td>1.00</td>
</tr>
<tr>
<td>Female</td>
<td>31 (59.6)</td>
<td>33 (58.9)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Efficacy

Sustained Virologic Response
- SVR rates were similar in Asian and white patients

Safety

Adverse Events

Table 2: Adverse Events in the International Cohort

<table>
<thead>
<tr>
<th></th>
<th>Asian (n = 52)</th>
<th>White (n = 56)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>16 (14.0)</td>
<td>13 (11.9)</td>
<td>0.39</td>
</tr>
<tr>
<td>Headache</td>
<td>30 (26.3)</td>
<td>26 (23.9)</td>
<td>0.25</td>
</tr>
<tr>
<td>Alopecia</td>
<td>27 (23.7)</td>
<td>17 (15.6)</td>
<td>0.14</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>5 (4.4)</td>
<td>11 (10.1)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Acknowledgments

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References

3. Results for Asian and white patients with G3 infection were similar (75% and 74.5%, respectively) and did not differ despite genetic

Conclusions

- SVR rates were similar in Asian and white patients with CHC G2 or G3 infection.
- The encouraging rates of SVR in the low-dose arm suggest that physicians can confidently reduce the PEG-IFN alfa-2b dose for patients who do not tolerate the standard-of-care regimen.

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