Phase 3

Treatment Naïve, Chronic HCV

Peginterferon alfa-2b + Ribavirin in GT 1-6
(Flat versus Weight-Based Ribavirin Dosing)

WINR Study

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose)
WIN-R Study: Design

- **Study**
  - Prospective, randomized, open-label trial

- **Subjects**
  - N = 5027 with chronic hepatitis C (4913 analyzed)
  - Treatment naïve adult patients (Age 18-70)

- **Treatment Regimens**
  - Peginterferon alfa-2b: 1.5 µg/kg/wk + Wt-based* Ribavirin: 800-1400 mg/d
  - Peginterferon alfa-2b: 1.5 µg/kg/wk + Flat-dose Ribavirin: 800 mg/d

- **Treatment Duration**
  - Genotypes 1,4,5,6: duration of 48 weeks
  - Genotypes 2,3: duration of 24 or 48 weeks

- **Primary Endpoint**
  - Undetectable serum HCV RNA at end of treatment (ETR)
  - Undetectable serum HCV RNA 24 weeks after cessation of treatment (SVR)

*Weight-based ribavirin dosing: < 65 kg: 800 mg/d; 65-85 kg: 1000 mg/d; >85-105 kg: 1200 mg/d; >105 kg: 1400 mg/d

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose)
WIN-R Study: Design

**Week 0**: Peginterferon alfa-2b + Ribavirin (weight-based) (n = 2111)
- SVR24

**Week 24**: Peginterferon alfa-2b + Ribavirin (flat dose) (n = 2144)
- SVR24

**Week 48**: Peginterferon alfa-2b + Ribavirin (weight-based) (n = 333)
- SVR24

**Week 72**: Peginterferon alfa-2b + Ribavirin (flat dose) (n = 335)
- SVR24

**Drug Dosing**
Peginterferon alfa-2b: 180 µg once weekly
Weight-based Ribavirin (in 2 divided doses):
- 800 mg/d if < 65 kg; 1000 mg/d if 65-85 kg; 1200 mg/d if >85-105 kg; 1400 mg/d if >105 kg
Flat-dose Ribavirin (in 2 divided doses): 800 mg/day

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose) WIN-R Study: Results

SVR 24, by Genotype and Treatment Regimen

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Weight-Based Ribavirin</th>
<th>Flat Dose Ribavirin</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>44/938/2121</td>
<td>41/852/2102</td>
<td>.008</td>
</tr>
<tr>
<td>GT-1</td>
<td>34/447/1313</td>
<td>29/377/1305</td>
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<td>GT-2,3</td>
<td>62/479/775</td>
<td>60/462/777</td>
<td>.252</td>
</tr>
</tbody>
</table>

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose)
WIN-R Study: Results

All Treated: SVR24 by Weight Distribution

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose)
WIN-R Study: Results

Sustained Virologic Response (SVR) by Weight Distribution

African American Genotype 1

Conclusion: “Peginterferon alfa-2b plus weight-based ribavirin is more effective than flat-dose ribavirin, particularly in genotype 1 patients, providing equivalent efficacy across all weight groups. Ribavirin 1400 mg/day is appropriate for patients 105 to 125 kg. For genotype 2/3 patients, 24 weeks of treatment with flat-dose ribavirin is adequate; no evidence of additional benefit of extending treatment to 48 weeks was demonstrated.”

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

Hepatitis Web Study

http://depts.washington.edu/hepstudy/

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