Phase 3

Treatment Naïve, Chronic HCV

Peginterferon alfa-2a

versus

Interferon alfa-2a

Peginterferon alfa-2a versus Interferon alfa-2a Study Features

- **Study**
  - Randomized, open label, parallel dose, phase 3 trial
  - 36 international centers

- **Subjects**
  - N = 531 with chronic hepatitis C
  - Treatment naïve
  - Any genotype (62% with genotype 1)
  - 18 years of age or older

- **Regimens**
  - Peginterferon alfa-2a: 180 μg 1x/week x 48 weeks
  - Interferon alfa-2a: 6 million units 3x/week x 12 weeks, then 6 million units 3x/week x 36 weeks

- **Primary Endpoint: Sustained Virologic Response (SVR24)**
  - SVR = undetectable serum HCV RNA 24 weeks after 48-week treatment
  - Undetectable serum HCV RNA = less than 100 copies/ml

Peginterferon alfa-2a versus Interferon alfa-2a Study Design

<table>
<thead>
<tr>
<th>Week</th>
<th>0</th>
<th>24</th>
<th>48</th>
<th>72</th>
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</thead>
</table>

N = 267

Peginterferon alfa-2a

SVR24

N = 264

Interferon alfa-2a

SVR24

Drug Dosing

Peginterferon alfa-2a: 180 µg once weekly

Interferon alfa-2a: 6 million units 3x/week x 12 weeks, then 6 million units 3x/week x 36 weeks

Peginterferon alfa-2a versus Interferon alfa-2a
Study Results

Virologic Responses by Treatment Regimen (ITT Analysis)

Peginterferon alfa-2a versus Interferon alfa-2a
Study Results

Independent Factors Associated with SVR, Multiple Regression Analysis

- Age ≤ 40 years
- No cirrhosis or bridging fibrosis
- Body-surface area ≤ 2 m²
- Treatment with peginterferon alfa-2a
- HCV RNA level ≤ 2 million copies/ml
- Pretreatment ALT quotient > 3
- HCV genotype other than type 1

Conclusions: “In patients with chronic hepatitis C, a regimen of peginterferon alfa-2a given once weekly is more effective than a regimen of interferon alfa-2a given three times weekly.”

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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