Glecaprevir-Pibrentasvir x 8 or 12 Weeks in GT1 Non-cirrhotics

ENDURANCE-1

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1 ENDURANCE-1: Study Features

### ENDURANCE-1 Trial

- **Design:** Randomized, open-labeled, phase 3 trial to evaluate the safety and efficacy of the fixed-dose combination of glecaprevir-pibrentasvir for 8 versus 12 weeks in treatment-naïve or treatment-experienced adults with GT 1 chronic HCV infection without cirrhosis

- **Key Eligibility Criteria**
  - Chronic HCV GT 1
  - Age ≥18
  - HCV RNA ≥1,000 IU/mL at screening
  - Naïve or treated with peginterferon +/- ribavirin (PR) or PR +/- sofosbuvir
  - Absence of cirrhosis
  - HIV co-infection allowed; chronic HBV coinfection excluded

- **Primary End-Point:** SVR12

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1
ENDURANCE-1: Study Design

Abbreviations: GLE-PIB = Glecaprevir-pibrentasvir

Drug Dosing
Glecaprevir-pibrentasvir (100/40 mg) fixed-dose combination: three pills (300/120 mg) once daily

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1
ENDURANCE-1: Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>GLE-PIB 8 weeks (n = 351)</th>
<th>GLE-PIB 12 weeks (n = 352)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, (range), years</td>
<td>53 (19-84)</td>
<td>52 (21-77)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>167 (48)</td>
<td>176 (50)</td>
</tr>
<tr>
<td>Black race, n (%)</td>
<td>14 (4)</td>
<td>13 (4)</td>
</tr>
<tr>
<td>HCV subtype 1a, n (%)</td>
<td>151 (43)</td>
<td>144 (41)</td>
</tr>
<tr>
<td>Body mass index, median kg/m² (range)</td>
<td>25 (18-41)</td>
<td>25 (18-54)</td>
</tr>
<tr>
<td>Median HCV RNA, log_{10} IU/mL (range)</td>
<td>6.1 (1.2-7.6)</td>
<td>6.1 (3.3-7.4)</td>
</tr>
<tr>
<td>Non-CC IL28B genotype, n (%)</td>
<td>249 (71)</td>
<td>266 (76)</td>
</tr>
<tr>
<td>Fibrosis Stage, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F0 or F1</td>
<td>296/348 (85)</td>
<td>298/351 (85)</td>
</tr>
<tr>
<td>F2</td>
<td>22/348 (6)</td>
<td>24/351 (7)</td>
</tr>
<tr>
<td>F3</td>
<td>30/348 (9)</td>
<td>29/351 (8)</td>
</tr>
<tr>
<td>Injection drug use, n (%)</td>
<td>98 (28)</td>
<td>98 (28)</td>
</tr>
<tr>
<td>HIV coinfection n (%)</td>
<td>15 (4)</td>
<td>18 (5)</td>
</tr>
</tbody>
</table>

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1
ENDURANCE-1: Baseline Characteristics

Primary Subset: excludes patients with HIV or previous treatment with sofosbuvir
Per-Protocol: excludes patients in primary subset who prematurely discontinued treatment or had virologic failure during treatment before week 8 and patients without virologic failure who had no HCV RNA value in the SVR12 assessment window.

Glecaprevir-Pibrentasvir for 8 or 12 weeks in Non-Cirrhotic GT 1

ENDURANCE-1: Baseline Characteristics

Conclusion: “Once-daily treatment with glecaprevir–pibrentasvir for either 8 weeks or 12 weeks achieved high rates of sustained virologic response among patients with HCV genotype 1 or 3 infection who did not have cirrhosis.”

*Note: ENDURANCE-1 was published in conjunction with ENDURANCE-3
This slide deck is from the University of Washington’s *Hepatitis C Online* and *Hepatitis Web Study* projects.

**Hepatitis C Online**

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**Hepatitis Web Study**


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