Elbasvir + Grazoprevir +/- RBV: HCV GT1 +/- HIV Coinfection
C-WORTHY Coinfection

Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection
C-WORTHY Coinfection: Study Features

C-WORTHY (Protocol 035) Trial

- **Design**: Randomized, open-label phase 2 trial examining the safety and efficacy of a fixed-dose combination of elbasvir plus grazoprevir, with or without ribavirin, in treatment-naïve HCV-monoinfected (part A) or HCV-HIV coinfected (part B) patients without cirrhosis

- **Entry Criteria**
  - Chronic HCV Genotype 1
  - 18 years or older
  - HCV RNA ≥10,000 IU/mL
  - No prior treatment
  - No cirrhosis
  - Part B: well-controlled HIV infection (on antiretroviral therapy ≥8 weeks, HIV RNA undetectable x ≥24 weeks and CD4 count ≥300 cells/mm³)

- **Primary End-Point**: SVR12

Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection C-WORTHY Coinfection: Study: Study Design Part A

<table>
<thead>
<tr>
<th>Week</th>
<th>0</th>
<th>12</th>
<th>24</th>
</tr>
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</tbody>
</table>

### Group A
- **Treatment-Naive HCV Monoinfected**
  - **n = 25**
    - GT 1a + 1b
    - **A1**
    - EBR (20 mg) + GZR + RBV
    - SVR12
  - **n = 27**
    - GT 1a + 1b
    - **A2**
    - EBR (50 mg) + GZR + RBV
    - SVR12
  - **n = 13**
    - GT 1b
    - **A3**
    - EBR (50 mg) + GZR
    - SVR12

### Abbreviations:
- EBR = elbasvir
- GZR = grazoprevir
- RBV = ribavirin

### Drug Dosing
- Elbasvir (20 mg or 50 mg) once daily
- Grazoprevir (100 mg) once daily
- Ribavirin (weight-based and divided bid): 800 to 1400 mg/day

Elbasvir+ Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection
C-WORTHY Coinfection: Study: Study Design Part B

Abbreviations: EBR = elbasvir; GZR = grazoprevir; RBV = ribavirin

Drug Dosing
Elbasvir (50 mg) once daily
Grazoprevir (100 mg) once daily
Ribavirin (weight-based and divided bid): 800 to 1400 mg/day

Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection
C-WORTHY Coinfection: Results

C-WORTHY: SVR12 Results by Treatment and HIV Coinfection Status

<table>
<thead>
<tr>
<th>Treatment Duration</th>
<th>Ribavirin Status</th>
<th>HCV Monoinfected</th>
<th>HCV-HIV Coinfected</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 weeks</td>
<td>(+ Ribavirin)</td>
<td>24/30</td>
<td>26/30</td>
</tr>
<tr>
<td>12 weeks</td>
<td>(+ Ribavirin)</td>
<td>79/85</td>
<td>80/87</td>
</tr>
<tr>
<td></td>
<td>(- Ribavirin)</td>
<td>43/44</td>
<td>93/98</td>
</tr>
<tr>
<td>12 weeks</td>
<td>(+ Ribavirin)</td>
<td>28/29</td>
<td>97/98</td>
</tr>
<tr>
<td></td>
<td>(- Ribavirin)</td>
<td>26/30</td>
<td>87/98</td>
</tr>
</tbody>
</table>

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C-WORTHY Coinfection: Study: Results

C-WORTHY: SVR12 Rates by HCV GT1 Subtype and Use of Ribavirin

Elbasvir + Grazoprevir +/- RBV in HCV GT1 +/- HIV Coinfection
C-WORTHY Coinfection: Study Features

**Interpretation**: “Once-daily grazoprevir plus elbasvir with or without ribavirin for 12 weeks in previously untreated HCV-mono-infected and HIV/HCV-co-infected patients without cirrhosis achieved SVR12 rates of 87-98%. These results support the ongoing phase 3 development of grazoprevir plus elbasvir.”