Phase 2

Sofosbuvir + (Ledipasvir or GS-9669) +/- Ribavirin in GT-1

ELECTRON Trial (Arms 12-17 & 22)

Sofosbuvir + (Ledipasvir or GS-9669) +/- Ribavirin in GT1 ELECTRON Trial (Arms 12-17 & 22): Features

**ELECTRON Trial (Arms 12-17 & 22)**

- **Design**: Open-label, phase 2, using sofosbuvir plus [ledipasvir or GS-9669] with or without ribavirin in treatment-naïve and treatment-experienced GT1

- **Setting**: two hepatitis treatment centers in New Zealand

- **Entry Criteria**
  - Chronic HCV genotype 1
  - HCV RNA >50,000 IU/mL
  - Age >18 years

- **Patient Characteristics (range in different treatment arms)**
  - n = 113 patients enrolled
  - Three of seven groups were treatment naïve
  - Four of seven groups were treatment experienced with prior null response
  - Two groups of seven groups were treatment experienced and cirrhotic
  - Three treatment arms used fixed dose ledipasvir-sofosbuvir

- **Primary End-Point**: SVR12
Sofosbuvir + (Ledipasvir or GS-9669) +/- Ribavirin in GT1 ELECTRON Trial Arms (12-17 & 22): Design

<table>
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<th>Week</th>
<th>Noncirrhotic Treatment Naive</th>
<th>Noncirrhotic Null responder</th>
<th>Cirrhotic Null responder</th>
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<td>n = 25 LDV + SOF + RBV</td>
<td>n = 9 LDV + SOF + RBV</td>
<td>n = 10 LDV-SOF</td>
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<td>SVR12</td>
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**Abbreviations:** LDV = ledipasvir; SOF = sofosbuvir; RBV = ribavirin

**Drug Dosing**

Sofosbuvir: 400 mg once daily; Ledipasvir: 90 mg once daily; GS-9669 = 500 mg once daily
Ledipasvir-sofosbuvir (90/400 mg): fixed dose combination one pill once daily
Ribavirin (weight-based and divided bid): 1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg

Sofosbuvir + (Ledipasvir or GS-9669) +/- Ribavirin in GT1 ELECTRON Trial (Arms 12-17 & 22): Results

ELECTRON TRIAL, SVR 12 by Treatment Regimen

*All regimens 12 weeks except treatment-naïve LDV-SOF + Ribavirin= 6 week regimen

**Conclusions:** “The combination of sofosbuvir and a second direct-acting antiviral agent is highly effective in treatment-naïve patients with HCV genotype 1 infection and in patients that did not respond to previous treatment.”