

Treatment Naïve and Treatment Experienced

Sofosbuvir

ELECTRON (Overview): 6 parts, 22 arms

Source: Gilead Sciences, Inc

Sofosbuvir

Summary of ELECTRON Trials Design (1 of 2)

- **Part 1**

- Arm 1: Sofosbuvir + Ribavirin x 12 weeks (GT 2,3; naive)
- Arm 2: Sofosbuvir + Ribavirin x 12 weeks + Peginterferon for weeks 1-4 (GT 2,3; naive)
- Arm 3: Sofosbuvir + Ribavirin x 12 weeks + Peginterferon for weeks 1-8 (GT 2,3; naive)
- Arm 4: Sofosbuvir + Ribavirin + Peginterferon x 12 weeks (GT 2,3; naive)

- **Part 2**

- Arm 5: Sofosbuvir x 12 weeks (GT 2,3; naive)
- Arm 6: Sofosbuvir + Ribavirin + Peginterferon x 8 weeks (GT 2,3; naive)
- Arm 7: Sofosbuvir + Ribavirin x 12 weeks (GT 1; experienced null)

- **Part 3**

- Arm 8: Sofosbuvir + Ribavirin x 12 weeks (GT 1; naive)
- Arm 9: Sofosbuvir + Ribavirin x 12 weeks (GT 2,3; experienced)

- **Part 4**

- Arm 10: Sofosbuvir + Ribavirin x 8 weeks (GT 2,3; naive)
- Arm 11: Sofosbuvir + Ribavirin x 12 weeks (GT 2,3; naive)
- Arm 12: Sofosbuvir + Ledipasvir + Ribavirin x 12 weeks (GT 1, experienced null)
- Arm 13: Sofosbuvir + Ledipasvir + Ribavirin x 12 weeks (GT 1, naive)

Sofosbuvir

Summary of ELECTRON Trials Design (2 of 2)

- **Part 5**

- Arm 14: Sofosbuvir + GS-9669 + Ribavirin x 12 weeks (GT 1; experienced null)
- Arm 15: Sofosbuvir + GS-9669 + Ribavirin x 12 weeks x 12 weeks (GT 1; naive)

- **Part 6**

- Arm 16: Sofosbuvir-Ledipasvir x 12 weeks (GT 1; experienced null; F4)
- Arm 17: Sofosbuvir-Ledipasvir + Ribavirin x 12 weeks (GT 1; experienced null; F4)
- Arm 18: Sofosbuvir-Ledipasvir x 12 weeks x 12 weeks (GT 2,3, naive)
- Arm 19: Sofosbuvir-Ledipasvir x 12 weeks x 12 weeks (GT 2,3, experienced)
- Arm 20: Sofosbuvir-Ledipasvir + Ribavirin x 12 weeks (GT 1, naïve, hemophiliacs)
- Arm 21: Sofosbuvir-Ledipasvir + Ribavirin x 6 weeks (GT 1, naive)
- Arm 22: Sofosbuvir-Ledipasvir x 6 weeks (GT 1, naive)

Treatment Naïve and Treatment Experienced

Sofosbuvir and Ribavirin +/- Peginterferon in GT 1-3 ELECTRON Trial (Arms 1-8)

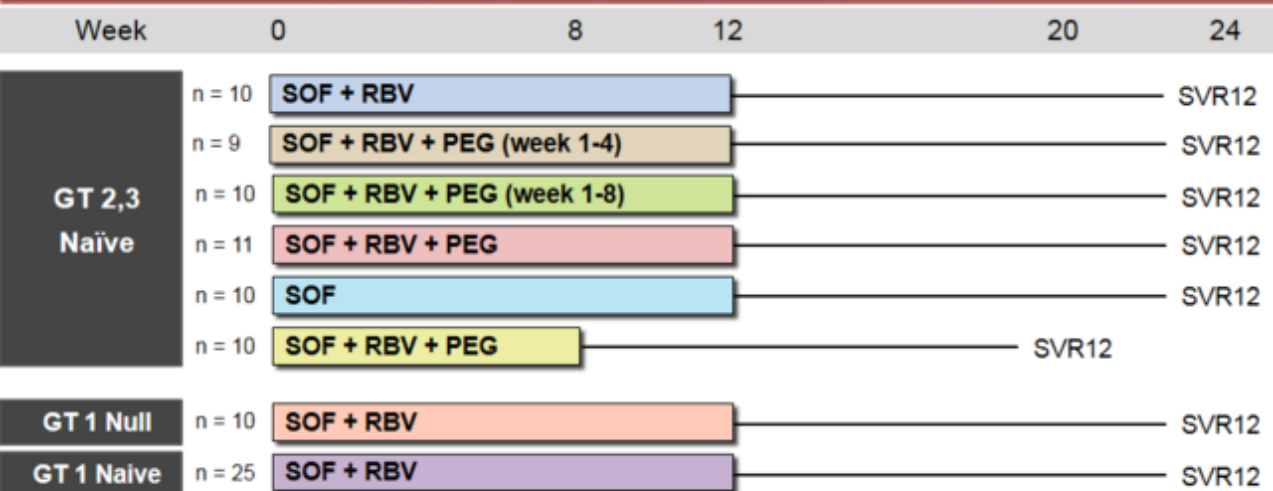
Gane EJ, et al. N Engl J Med. 2013;368:34-44.

Sofosbuvir and Ribavirin +/- Peginterferon in GT 1-3 ELECTRON Trial (Arms 1-8): Features

FUSION Trial: Features

- **Design:** Randomized, double-blind, phase 2a trial comparing different combinations of sofosbuvir and ribavirin with or without peginterferon
- **Setting:** 2 hepatitis C treatment centers in New Zealand
- **Entry Criteria**
 - HCV RNA > 50,000 IU/mL
 - No cirrhosis
 - Part 1: genotype 2,3
 - Part 2: genotype 1- Arms 1-6: GT 2 or 3; treatment-naïve
- **Study Arms**
 - Arms 1-6: genotype 2,3 treatment naïve: SOF + RBV +/- PEG
 - Arm 7: GT 1; treatment experienced, prior null responder: SOF + RBV
 - Arm 8: GT 1; treatment naïve: SOF + RBV
- **Primary End-Point:** SVR12

Sofosbuvir and Ribavirin +/- Peginterferon in GT 1-3 ELECTRON Trial (Arms 1-8): Design



Drug Dosing

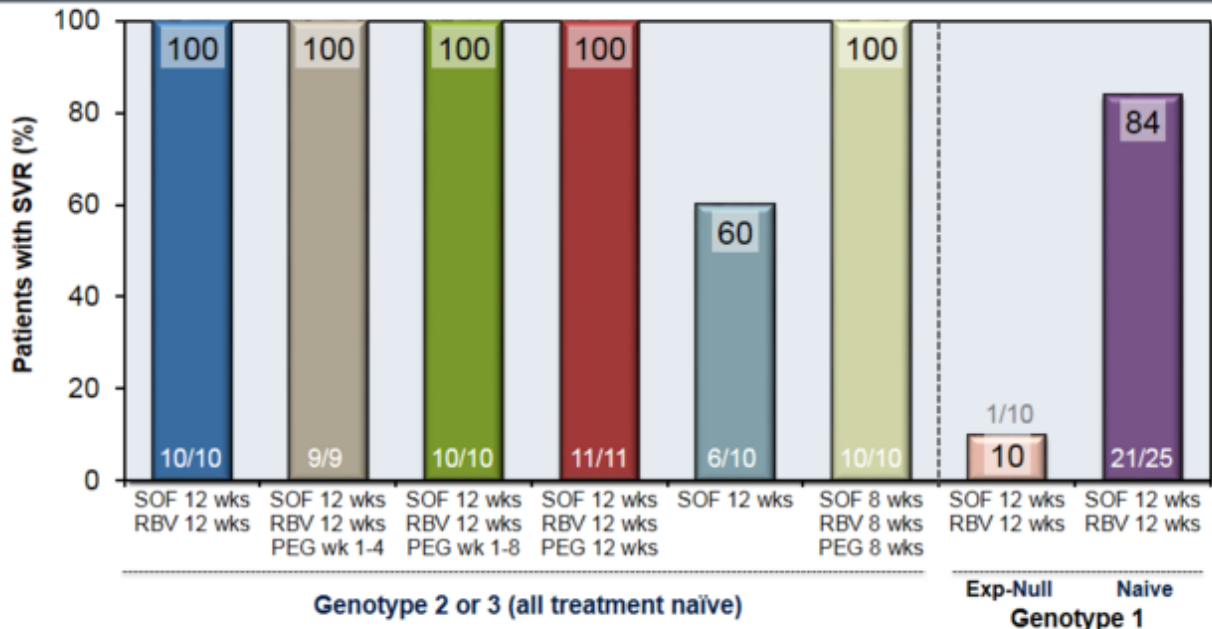
Sofosbuvir (SOF): 400 mg once daily

Ribavirin (RBV) weight-based and divided bid: 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

Peginterferon alfa-2a (PEG): 180 µg once weekly

Sofosbuvir and Ribavirin +/- Peginterferon in GT 1-3 ELECTRON Trial (Arms 1-8): Results

ELECTRON: SVR 12, by Treatment Regimen



Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 ELECTRON Trial: Conclusions

Conclusions: “Sofosbuvir plus ribavirin for 12 weeks may be effective in previously untreated patients with HCV genotype 1, 2, or 3 infection.”

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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