Sofosbuvir in Genotype 2,3 (Treatment-Experienced)
FUSION Trial

*Note: Published in tandem with POSITRON Trial (GT 2,3 Unable to receive PEG)

Sofosbuvir and Ribavirin for Chronic HCV
FUSION Trial

Study Features

- **Design**: Randomized, controlled, blinded phase 3 trial comparing 12 vs 16 weeks of sofosbuvir + ribavirin in HCV GT 2 or 3
- **Setting**: Setting: 67 sites in US, Canada, New Zealand, enrolled May-July 2012
- **Entry Criteria**
  - Treatment-experienced → failed prior interferon-based therapy (75-76% viral relapsers)
  - HCV RNA ≥ 10,000 IU/ml
- **Patient Characteristics**
  - N = 201 HCV-monoinfected patients
  - HCV Genotype: 2 (34%); 3 (63%)
  - IL28B Genotype: 70% non-CC
  - Age and Sex: mean age 54 (range 24-70); 70% male
  - Race: 87% white; 3% black
  - Liver disease: 34% had cirrhosis
- **Primary end-points**: Efficacy (SVR12) and safety

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web study

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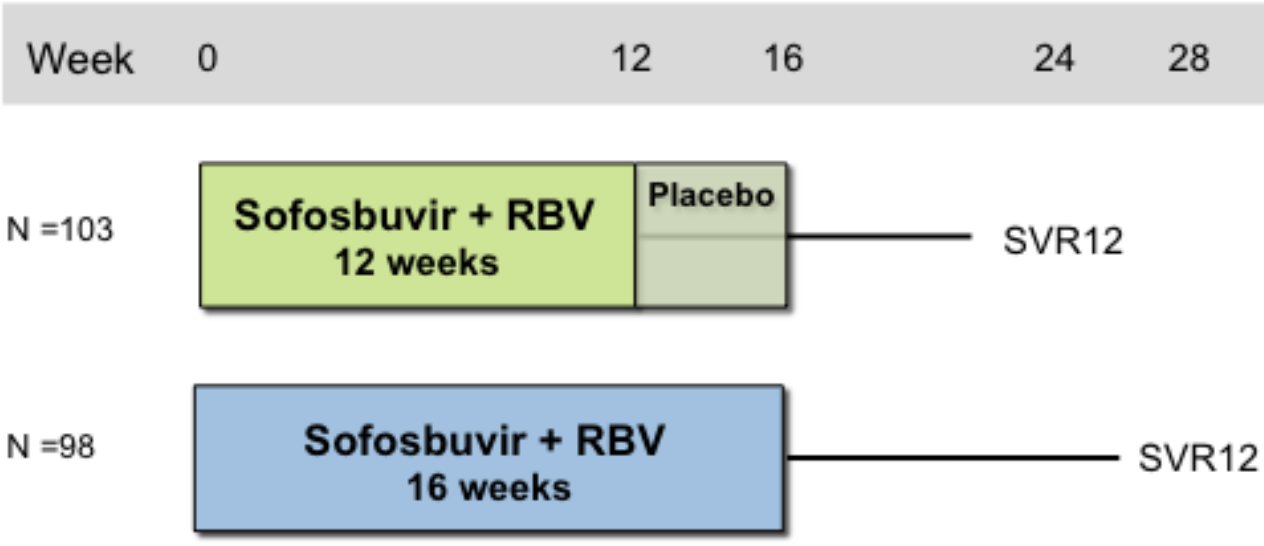


Drug Dosing

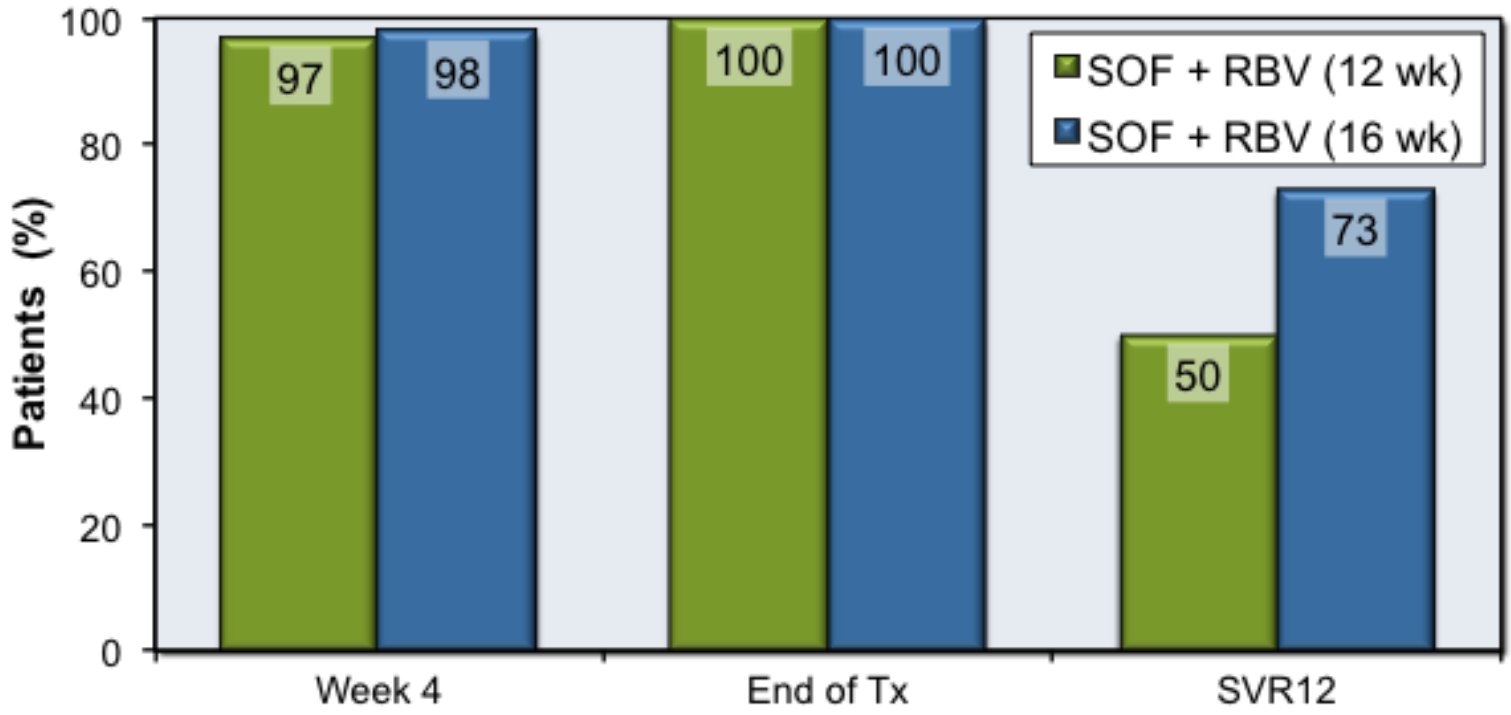
Sofosbuvir 400 mg once daily

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

Source: Jacobson I, et al. N Engl J Med. 2013;368:1867-77.

Sofosbuvir for Chronic HCV Infection GT 2,3
FUSION Study: Results

Percentage of Patients with HCV RNA <25 IU/ml by Study Timepoint

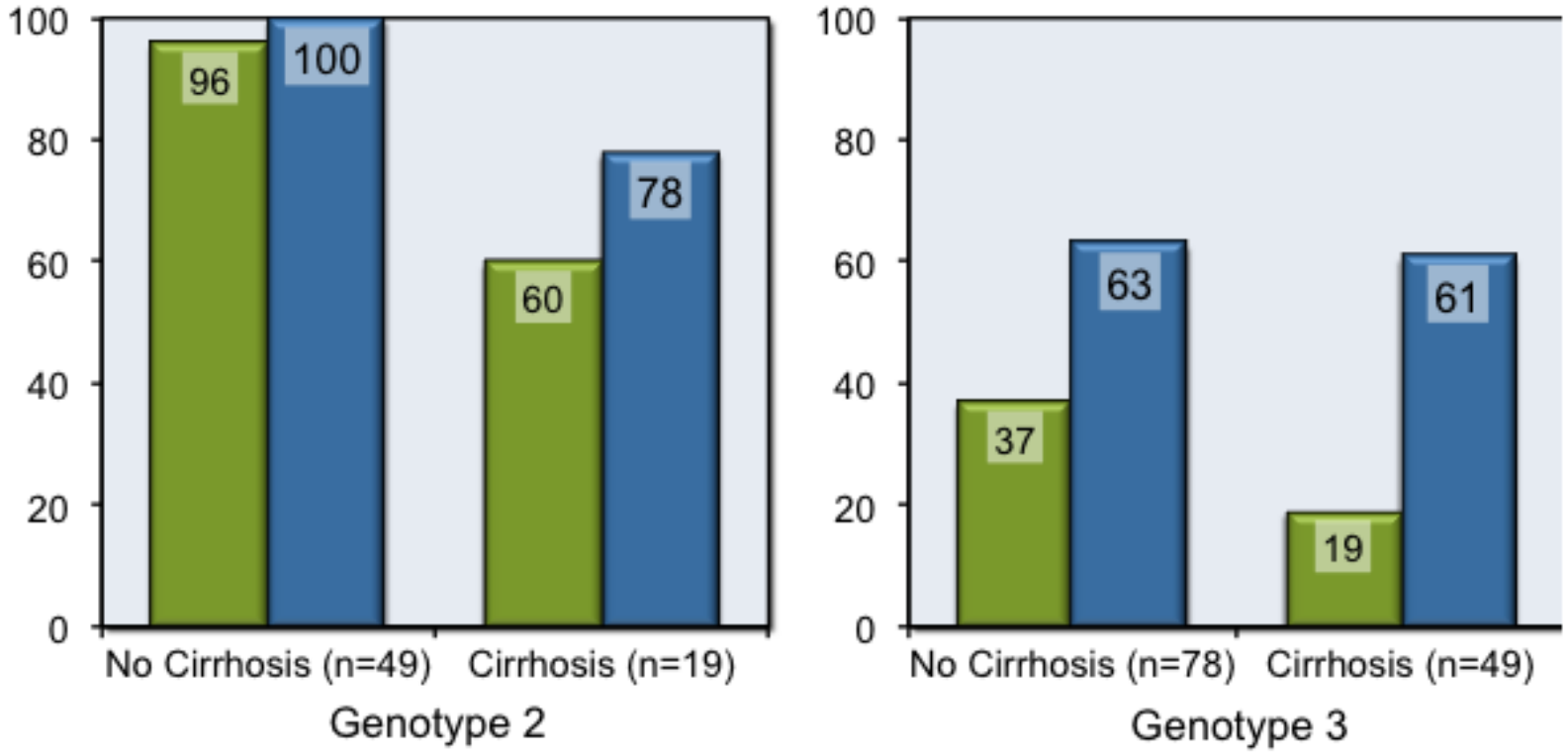


Sof = Sofosbuvir; RBV = Ribavirin

Source: Jacobson I, et al. N Engl J Med. 2013;368:1867-77.

Sofosbuvir for Chronic HCV Infection GT 2,3
FUSION Study: Results

SVR12 by Genotype & Cirrhosis



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Sofosbuvir and Ribavirin for Chronic HCV
FUSION Trial: Conclusions

Conclusion: "Our findings suggest that 12 weeks of treatment with sofosbuvir and ribavirin can be an effective option for patients with HCV genotype 2 infection. However, for patients with genotype 3 infection, particularly those who have cirrhosis or who have not had a response to prior treatment with interferon, extending the duration of treatment to 16 weeks may provide an additional benefit."

Source: Jacobson I, et al. N Engl J Med. 2013;368:1867-77.