

Treatment Naïve

Telaprevir + Peginterferon + Ribavirin for GT1 PROVE1 Study

McHutchison JG, et. al. N Engl J Med. 2009;360:1827-38.

Telaprevir for Treatment-Naïve HCV Genotype 1

PROVE1: Study Feature

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- N = 236 randomized
- Randomized, double-blind, placebo-controlled
- Phase 2b trial
- Chronic HCV and treatment naïve
- All with Genotype 1
- Age = 18-65; HIV negative; HBsAg negative
- Setting: 37 centers in United States
- Randomized to one of four treatment groups

Drug Dosing

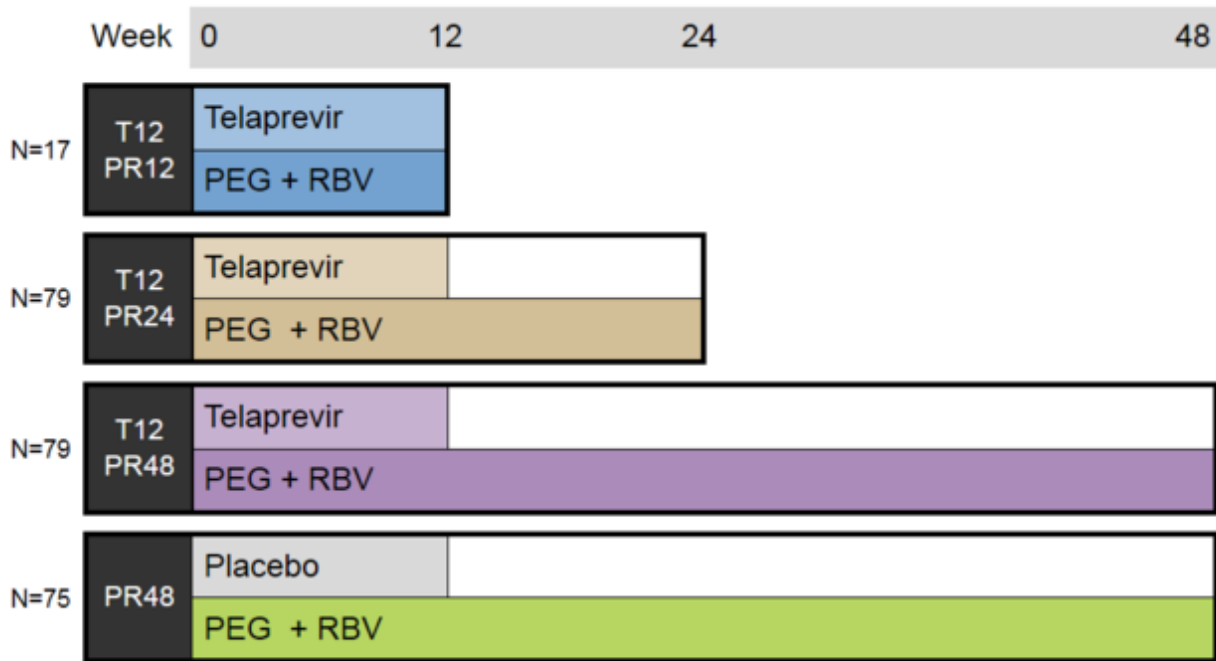
Telaprevir = 1250 mg on day 1, then 750 mg every 8 hours

Peginterferon alfa-2a = 180 µg weekly

Ribavirin = 1000 mg/day for wt < 75 kg; 1200 mg/day for wt ≥ 75 kg

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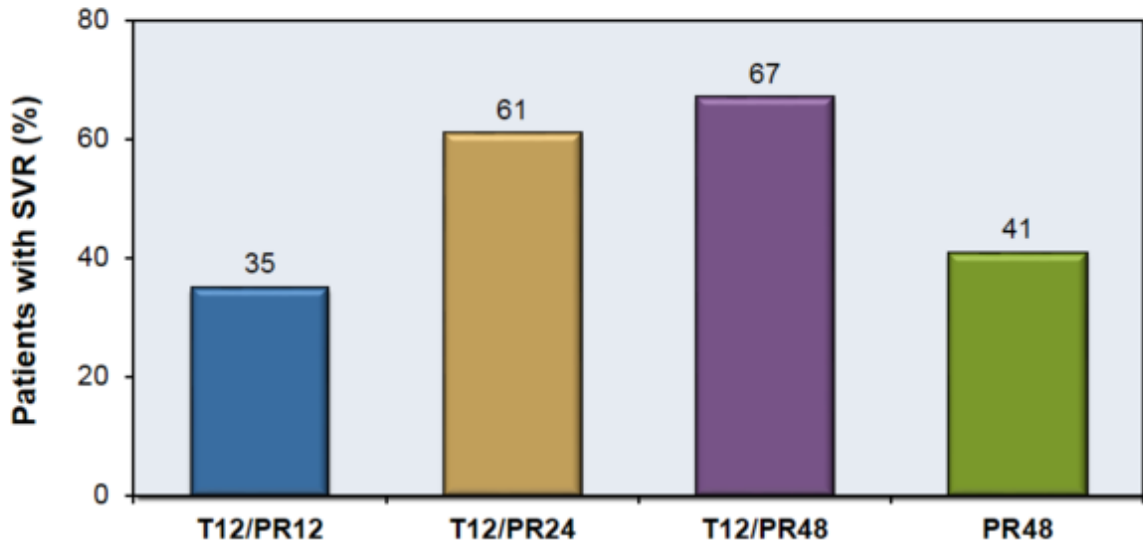
PROVE1 Study: Treatment Regimens



Telaprevir for Treatment-Naïve HCV Genotype 1

PROVE1 Study: Results

PROVE1: SVR24 by Regimen

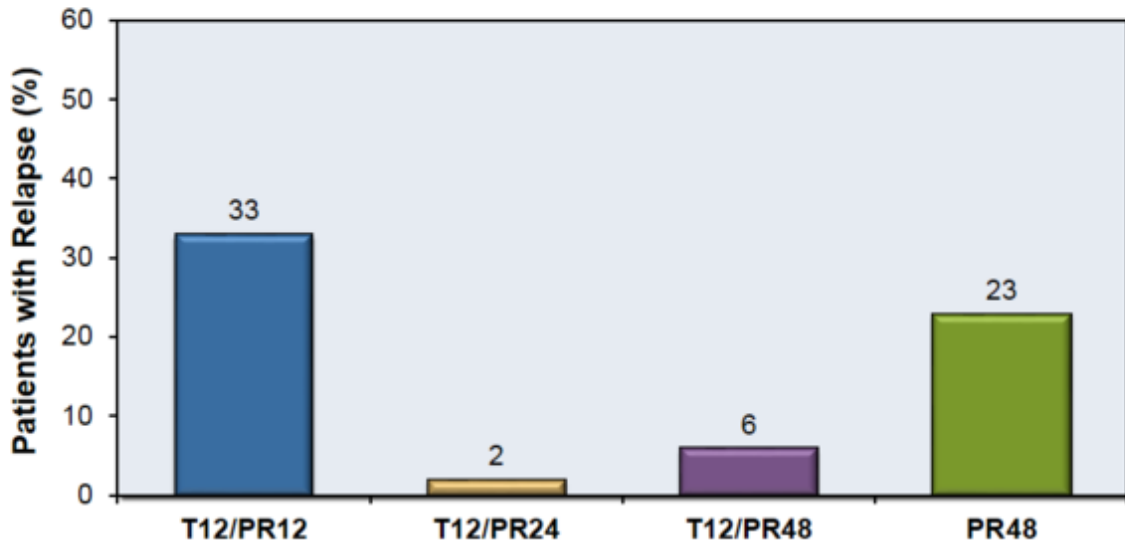


SVR = Sustained Virologic Response; T = Telaprevir; PR = Peginterferon + Ribavirin

Source: McHutchison JG, et. al. *N Engl J Med.* 2009;360:1827-38.

Telaprevir for Treatment-Naïve HCV Genotype 1 PROVE1 Study: Results

PROVE1: Percentage of Patients with Relapse by Regimen

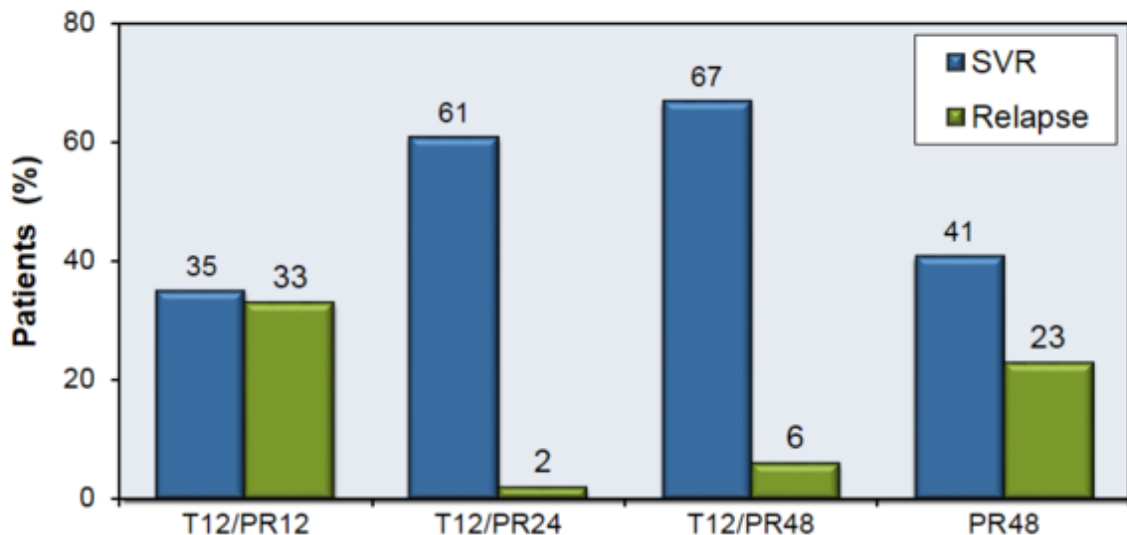


T = Telaprevir; PR = Peginterferon + Ribavirin

Source: McHutchison JG, et. al. *N Engl J Med.* 2009;360:1827-38.

Telaprevir for Treatment-Naïve HCV Genotype 1 PROVE1 Study: Results

PROVE1: Patients with SVR24 and Relapse by Regimen



SVR = Sustained Virologic Response; T = Telaprevir; PR = Peginterferon + Ribavirin

Telaprevir for Treatment-Naïve HCV Genotype 1 PROVE1 Study: Conclusions

Conclusions: “Treatment with a telaprevir-based regimen significantly improved sustained virologic response rates in patients with genotype 1 HCV, albeit with higher rates of discontinuation because of adverse events.”