

Treatment Naïve

Telaprevir in Treatment Naïve GT-1 PROVE2 Study

Hézode C, et al. N Engl J Med. 2009;360:1839-50.

Telaprevir for Treatment-Naïve HCV Genotype 1

PROVE2: Study Design

PROVE2: Study Features

- N = 334 enrolled and 323 received at least 1 dose
- Randomized, partially double-blind trial, placebo-controlled
- Phase 2b trial
- Chronic HCV and treatment naïve
- All with Genotype 1; 84% with HCV RNA \geq 800,000 IU/ml
- Age = 18-65 and HIV-negative
- Setting: 28 sites in Europe
- Randomized to one of 4 arms

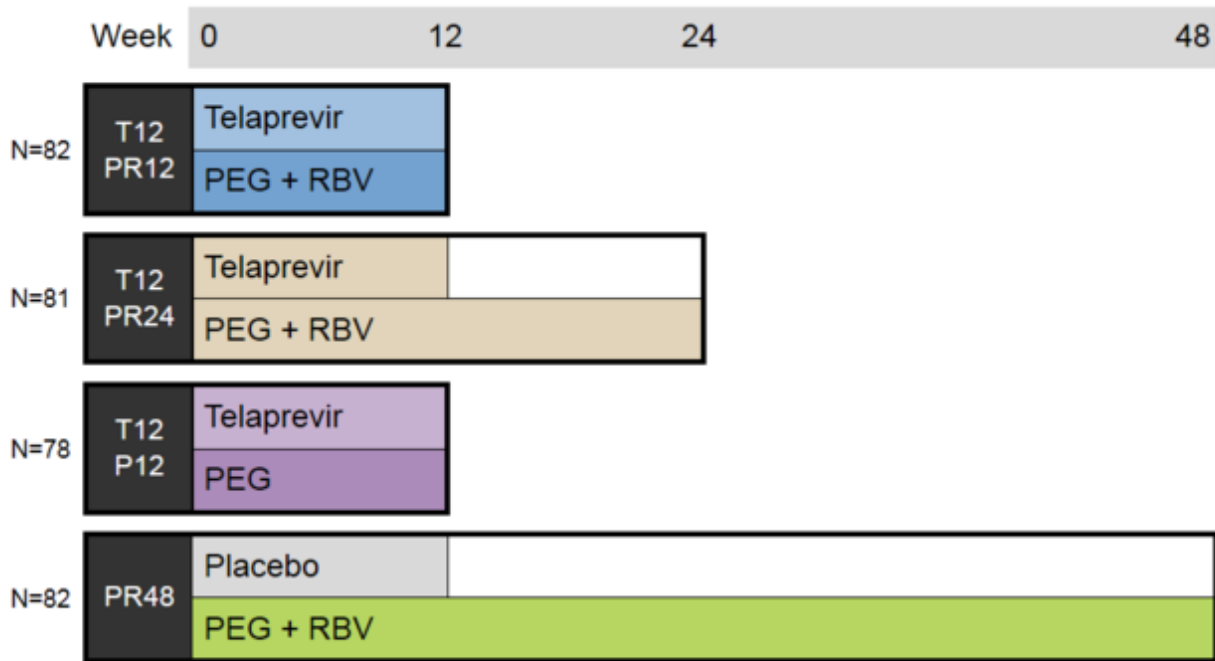
Drug Dosing

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

Peginterferon alfa-2a = 180 μ g weekly

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

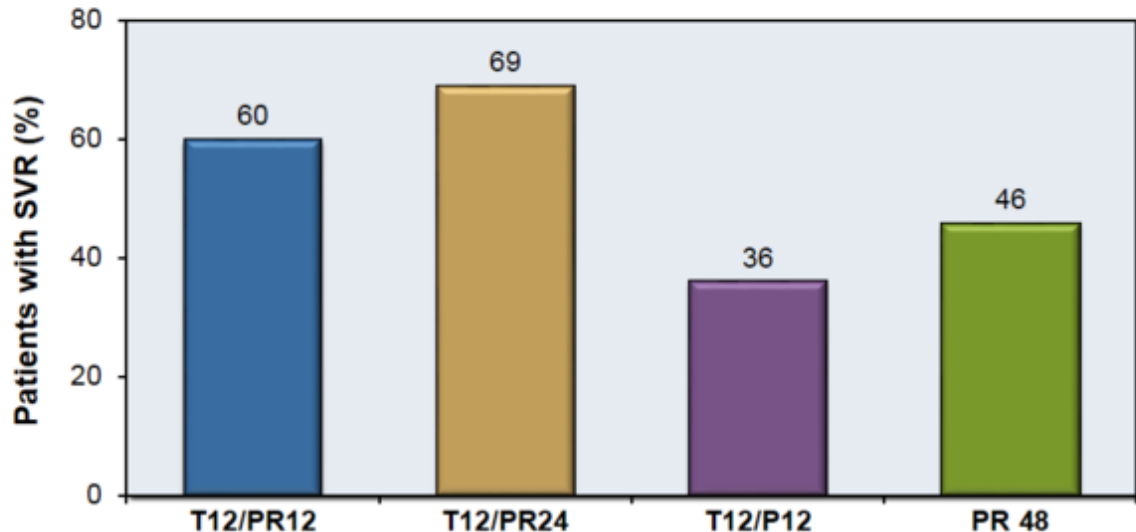
Telaprevir for Treatment-Naïve HCV Genotype 1 PROVE2 Study: Treatment Regimens



Telaprevir for Treatment-Naïve HCV Genotype 1

PROVE2 Study: Results

PROVE2: SVR24 by Regimen

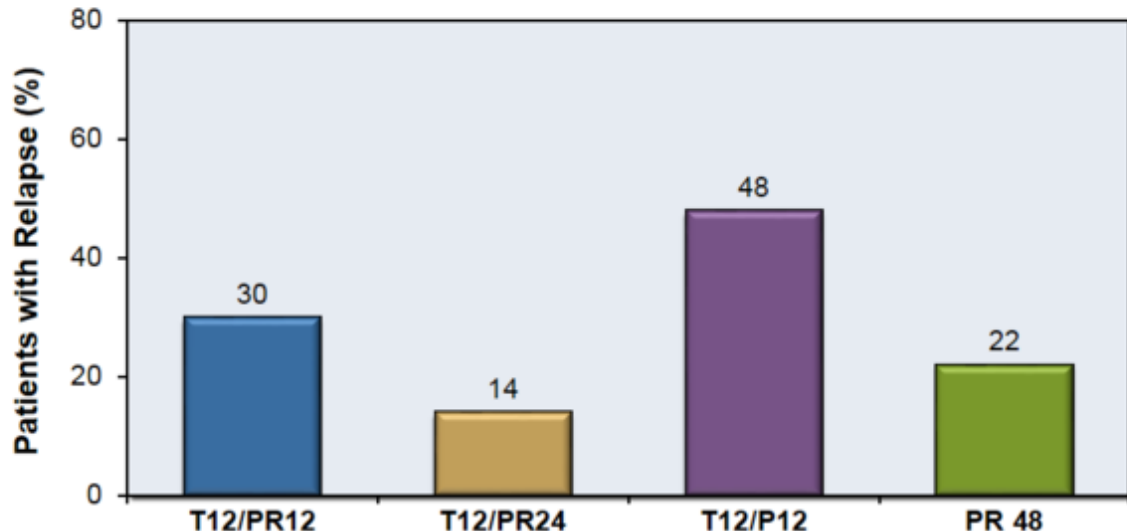


SVR = Sustained Virologic Response; T = Telaprevir; P = Peginterferon; PR = Peginterferon + Ribavirin

Telaprevir for Treatment-Naïve HCV Genotype 1

PROVE2 Study: Results

PROVE2: Patients with Relapse by Regimen

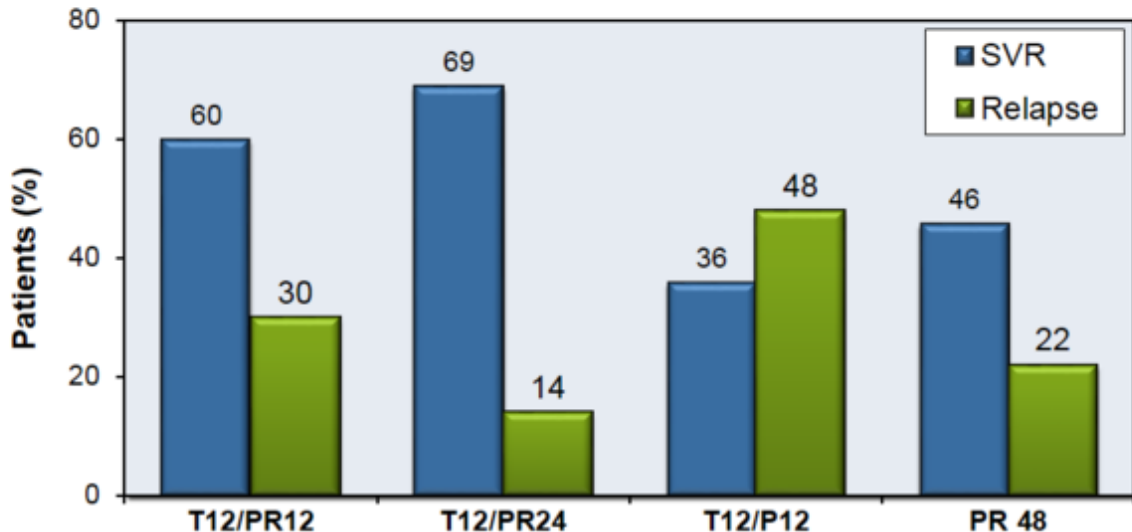


T = Telaprevir; P = Peginterferon; PR = Peginterferon + Ribavirin

Source: Hézode C, et al. *N Engl J Med.* 2009;360:1839-50.

Telaprevir for Treatment-Naïve HCV Genotype 1 PROVE2 Study: Results

PROVE2: Patients with SVR and Relapse by Regimen

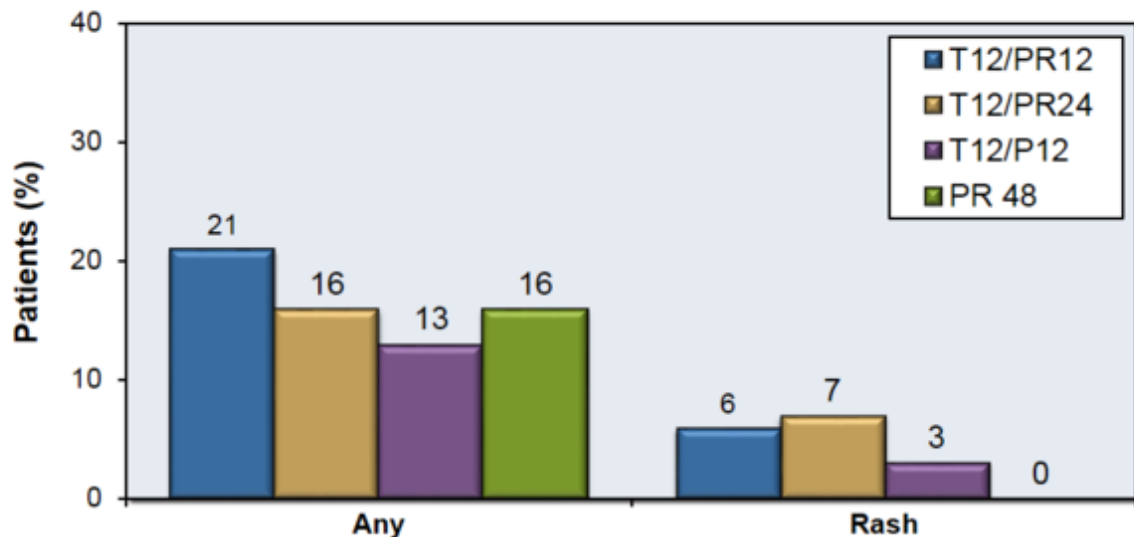


SVR = Sustained Virologic Response; T = Telaprevir; P = Peginterferon; PR = Peginterferon + Ribavirin

Source: Hézode C, et al. *N Engl J Med.* 2009;360:1839-50.

Telaprevir for Treatment-Naïve HCV Genotype 1 PROVE2 Study: Results

PROVE2: Severe (Grade 3) Adverse Events by Regimen



T = Telaprevir; P = Peginterferon; PR = Peginterferon + Ribavirin

Telaprevir for Treatment-Naïve HCV Genotype 1

PROVE2 Study: Conclusions

Conclusions: “In this phase 2 study of patients infected with HCV genotype 1 who had not been treated previously, one of the three telaprevir groups had a significantly higher rate of sustained virologic response than that with standard therapy. Response rates were lowest with the regimen that did not include ribavirin.”