

# Telaprevir in Treatment Experienced GT-1 PROVE3

McHutchison JG, et al. N Engl J Med. 2010;362:1292-303.

# Telaprevir for Treatment-Experienced HCV Genotype 1

## PROVE3 Study: Study Design

### PROVE3: Study Features

- Randomized, partially double-blind trial, placebo-controlled
- Phase 2b trial
- All with HCV and lack of SVR with Peginterferon + Ribavirin
- Eligible if 18 to 70 years of age
- All with Genotype 1; 92% with HCV RNA  $\geq$  800,000 IU/ml
- N = 465 enrolled and 453 received at least 1 dose
- Setting: 53 international sites (41 in US)
- Randomized to one of 4 arms

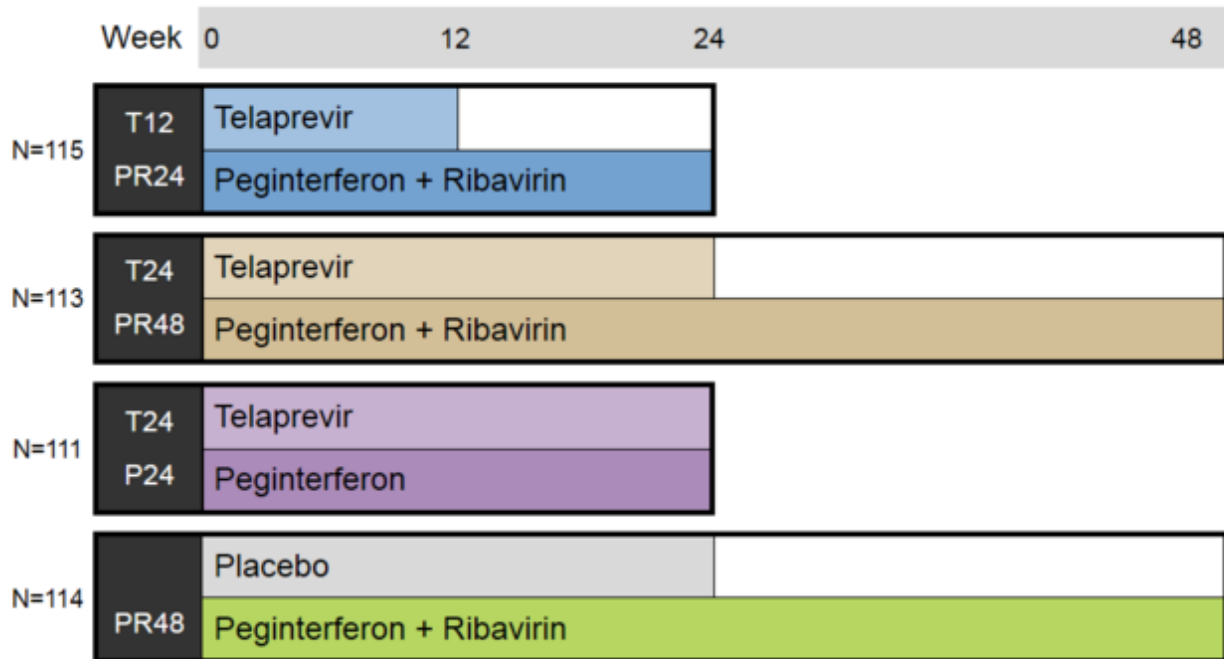
### Drug Dosing

Telaprevir = 1125 mg loading dose, then 750 mg every 8 hours

Peginterferon alfa-2a = 180  $\mu$ g weekly

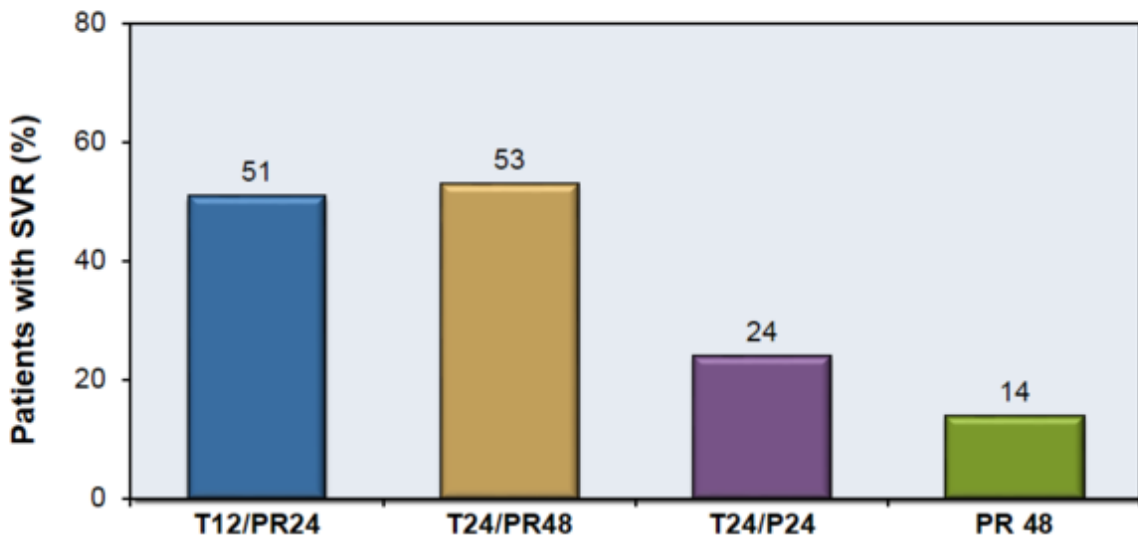
Ribavirin = 1000 mg/d for wt < 75 kg; 1200 mg/d for wt  $\geq$  75 kg

# Telaprevir for Treatment-Experienced HCV Genotype 1 PROVE3 Study: Treatment Regimens



# Telaprevir for Treatment-Experienced HCV Genotype 1 PROVE3 Study: Results

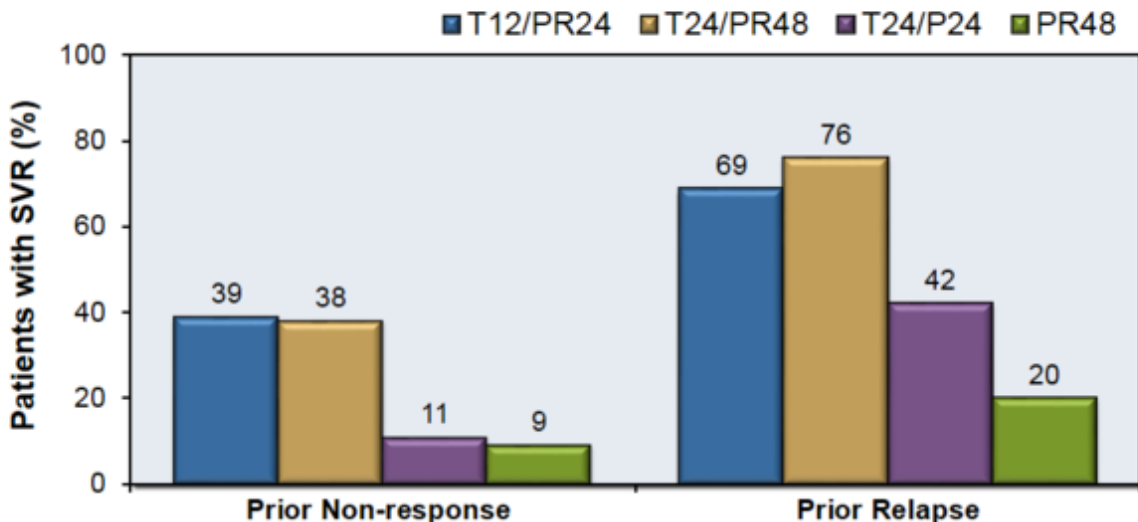
## PROVE3: SVR24 by Regimen



SVR = sustained virologic response; T = Telaprevir; P = Peginterferon; PR = Peginterferon + Ribavirin

# Telaprevir for Treatment-Experienced HCV Genotype 1 PROVE3 Study: Results Based on Prior History

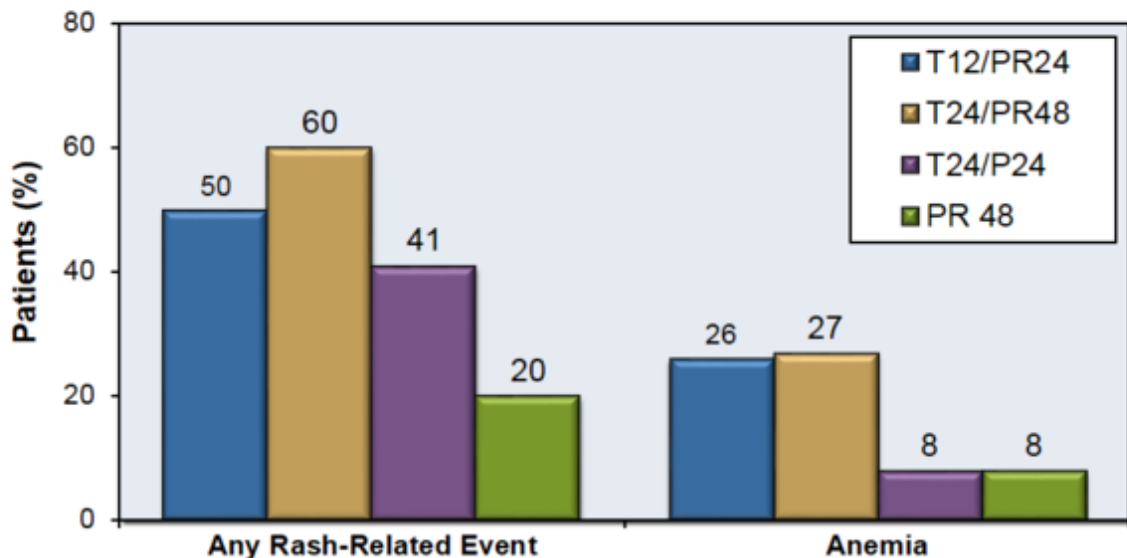
## PROVE3: SVR24 by Prior Response Status



SVR = sustained virologic response; T = Telaprevir; P = Peginterferon; PR = Peginterferon + Ribavirin

# Telaprevir for Treatment-Experienced HCV Genotype 1 PROVE3 Study: Results

## PROVE3: Adverse Events



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

Source: McHutchison JG, et al. *N Engl J Med.* 2010;362:1292-303.

# Telaprevir for Treatment-Experienced HCV Genotype 1 PROVE3 Study: Conclusions

**Conclusions:** “In HCV-infected patients in whom initial peginterferon alfa and ribavirin treatment failed, retreatment with telaprevir in combination with peginterferon alfa-2a and ribavirin was more effective than retreatment with peginterferon alfa-2a and ribavirin alone.”