

Treatment Naïve

Telaprevir BID versus q8 in Treatment Naïve GT-1 OPTIMIZE (Study C211)

Buti M, et al. Gastroenterology. 2013 Dec 4. [Epub ahead of print]

Twice Daily Telaprevir for Treatment-Naïve HCV Genotype 1

OPTIMIZE Study: Design

OPTIMIZE: Study Features

- N = 740 enrolled
- Randomized, double-blind, placebo-controlled, Phase 3 trial
- Genotype 1 HCV and treatment naïve
- 85% with HCV RNA \geq 800,000 IU/ml
- Randomized to one of 2 arms to compare bid and q8h telaprevir
- RVR = HCV RNA undetectable (<25 IU/ml) at week 4
- All patients received telaprevir for 12 weeks (bid or q8h)
- Patients with RVR received PR for 24 weeks
- Patients without RVR received PR for 48 weeks

Drug Dosing

Telaprevir = 1125 mg bid or 750 mg q8h

Peginterferon alfa-2a = 180 μ g weekly

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

Twice Daily Telaprevir for Treatment-Naïve HCV Genotype 1 OPTIMIZE Study: Treatment Regimens

Week 0 12 24 48

T12 bid
PR 24 or 48
(n = 369)

Telaprevir (bid)

PEG + RBV

If (-) RVR continue PEG + RBV

T12 q8h
PR 24 or 48
(n = 371)

Telaprevir (q8h)

PEG + RBV

If (-) RVR continue PEG + RBV

RVR = week 4 HCV RNA undetectable

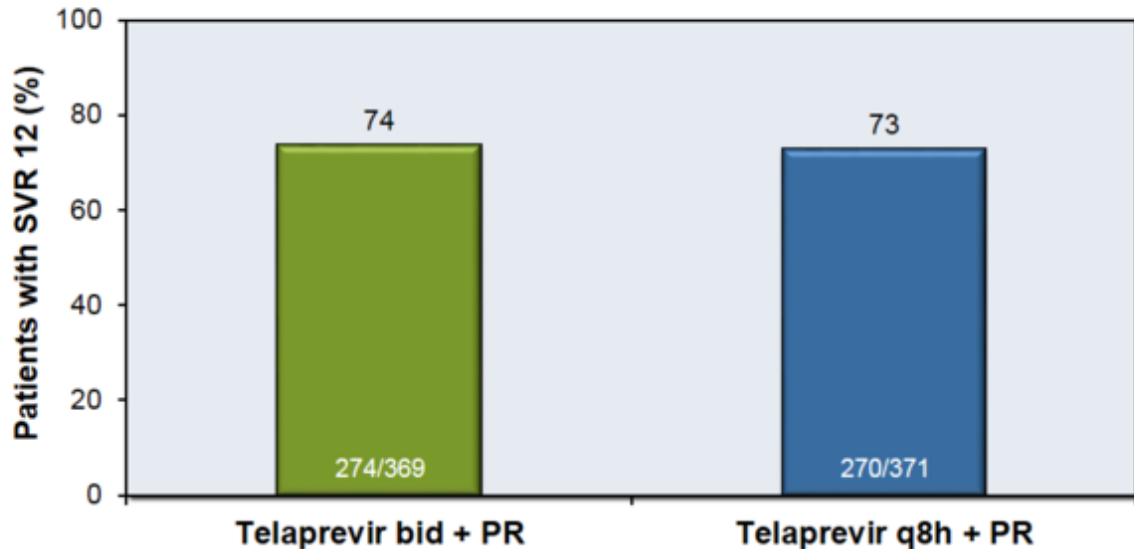
PEG = peginterferon; RBV = ribavirin

Therapy stopped if HCV RNA > 1000 IU/mL at week 4 or HCV RNA > 25 IU/mL at weeks 12, 24, 32, or 40

Twice Daily Telaprevir for Treatment-Naïve HCV Genotype 1

OPTIMIZE Study: Results

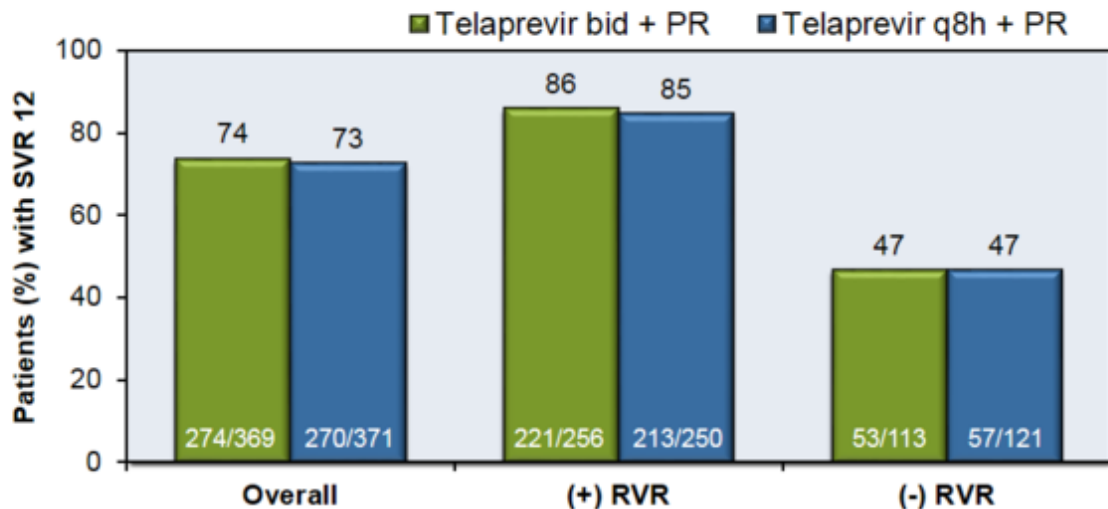
OPTIMIZE: SVR12 by Regimen



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

Twice Daily Telaprevir for Treatment-Naïve HCV Genotype 1 OPTIMIZE Study: Results

OPTIMIZE: SVR12 by Week 4 Virologic Response

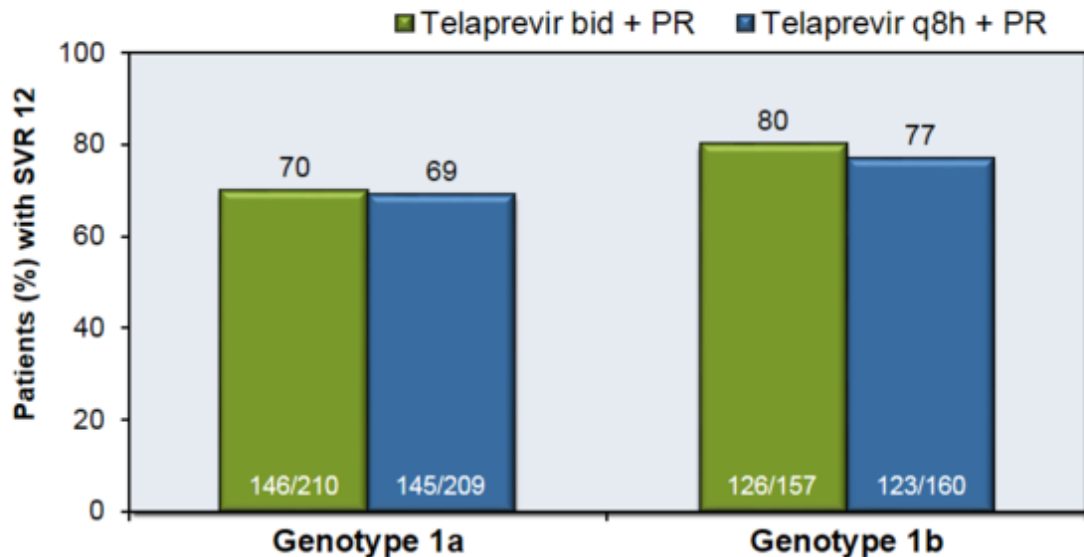


RVR = rapid virologic response (undetectable HCV RNA at week 4)

Abbreviations: SVR = sustained virologic response; PR = peginterferon + ribavirin

Twice Daily Telaprevir for Treatment-Naïve HCV Genotype 1 OPTIMIZE Study: Results

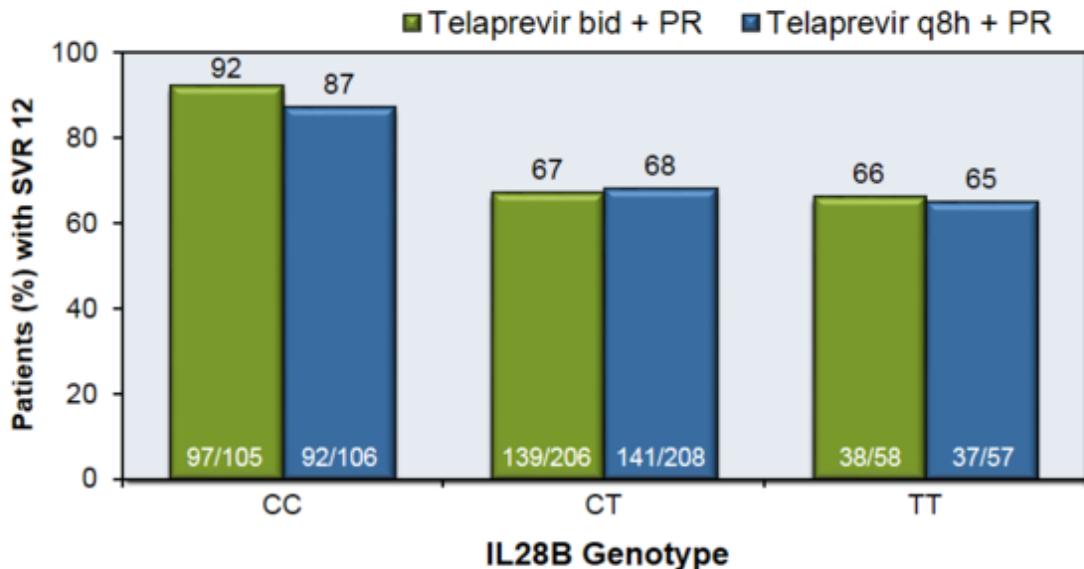
OPTIMIZE: SVR12 by Genotype 1 Subtype



Abbreviations: SVR = sustained virologic response; PR = peginterferon + ribavirin

Twice Daily Telaprevir for Treatment-Naïve HCV Genotype 1 OPTIMIZE Study: Results

OPTIMIZE: SVR12 by Host *IL28B* Genotype

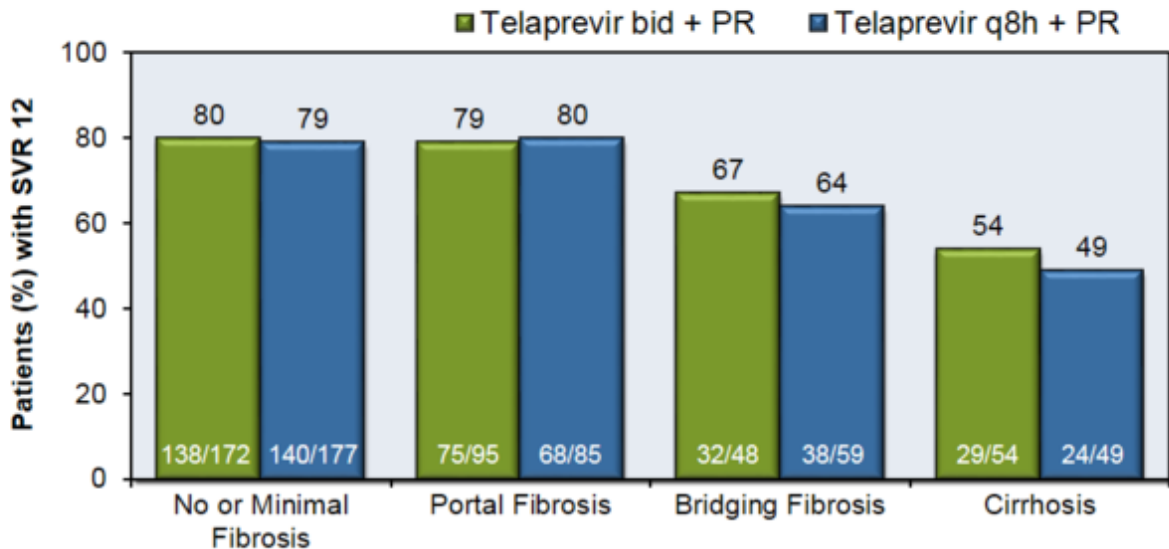


Abbreviations: SVR = sustained virologic response; PR = peginterferon + ribavirin

Source: Buti M, et al. *Gastroenterology*. 2013 Dec 4. [Epub ahead of print]

Twice Daily Telaprevir for Treatment-Naïve HCV Genotype 1 OPTIMIZE Study: Results

OPTIMIZE: SVR12 by Fibrosis Stage



Abbreviations: SVR = sustained virologic response; PR = peginterferon + ribavirin

Source: Buti M, et al. *Gastroenterology*. 2013 Dec 4. [Epub ahead of print]

Twice Daily Telaprevir for Treatment-Naïve HCV Genotype 1 OPTIMIZE Study: Conclusions

Conclusions: “Based on a phase 3 trial, telaprevir twice daily is noninferior to every 8 hours in producing SVR12, with similar levels of safety and tolerability. These results support use of telaprevir twice-daily in patients with chronic HCV genotype 1 infection, including those with cirrhosis.”