Treatment Naïve

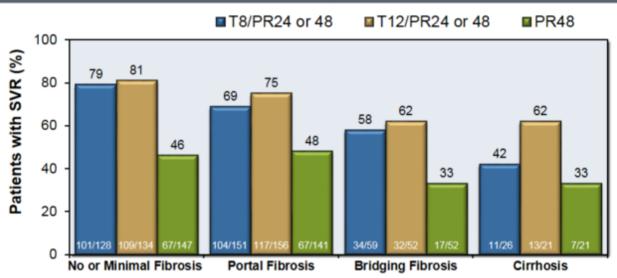
Telaprevir in Treatment Naïve GT-1 ADVANCE (Study 108)

Jacobson IM, et. al. N Engl J Med. 2011;364:2405-16.



Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE Study: Results by Fibrosis Stage

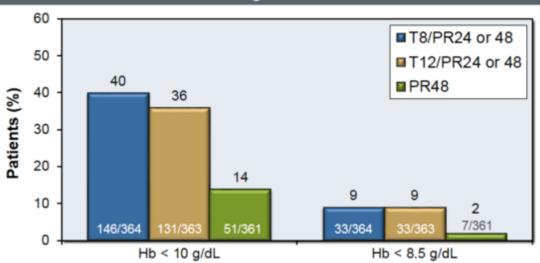
ADVANCE: SVR24 by Fibrosis Stage





Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE Study: Adverse Effects

ADVANCE: Percentage of Patients with Anemia



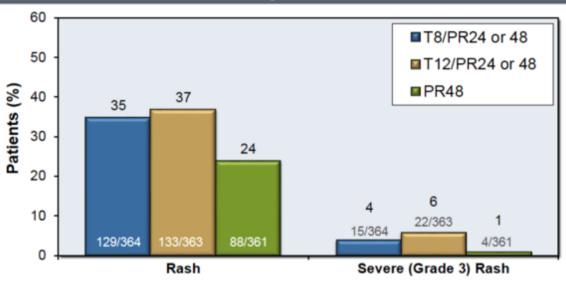
Hemoglobin (Hb) Nadir Through Week 12

T = Telaprevir; PR = Peginterferon + Ribavirin



Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE Study: Adverse Effects

ADVANCE: Percentage of Patients with Rash

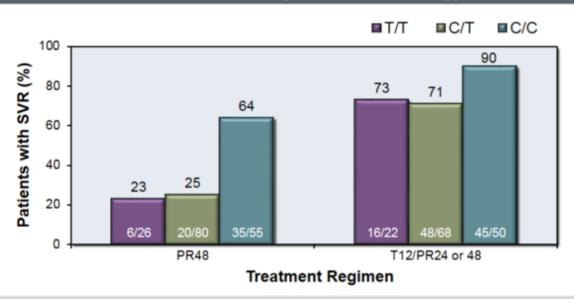


T = Telaprevir; PR = Peginterferon + Ribavirin



Telaprevir for Treatment-Naïve HCV Genotype 1 SVR Rates by *IL28B rs12979860* Genotype

ADVANCE: SVR24 by rs12979860 Genotype



PR48 = Peginteron/Ribavirin x 48 weeks PR/T12 = Peginteron/Ribavirin + Telaprevir x 12 weeks



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

Conclusions: "Telaprevir with peginterferon–ribavirin, as compared with peginterferon–ribavirin alone, was associated with significantly improved rates of sustained virologic response in patients with HCV genotype 1 infection who had not received previous treatment, with only 24 weeks of therapy administered in the majority of patients."



Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE: Study Design

ADVANCE: Study Features

- N = 1,088 enrolled
- Randomized, double-blind, placebo-controlled, Phase 3 trial
- Genotype 1 HCV and treatment naïve
- 77% with HCV RNA ≥ 800,000 IU/ml
- Randomized to one of 3 arms
- RVR = HCV RNA undetectable at week 4
- eRVR = HCV RNA undetectable at weeks 4 & 12
- Erythroid stimulating agents not allowed
- Telaprevir-treated patients without eRVR received PR up to week 48

Drug Dosing

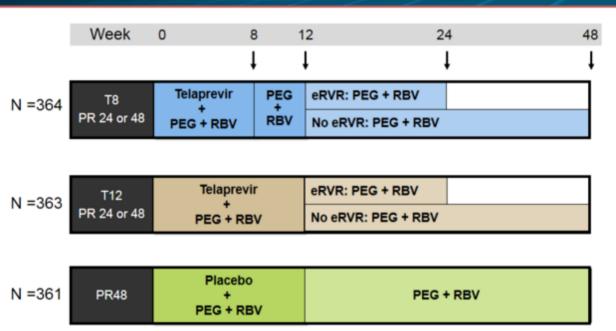
Telaprevir = 750 mg every 8 hours

Peginterferon alfa-2a = 180 µg weekly

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



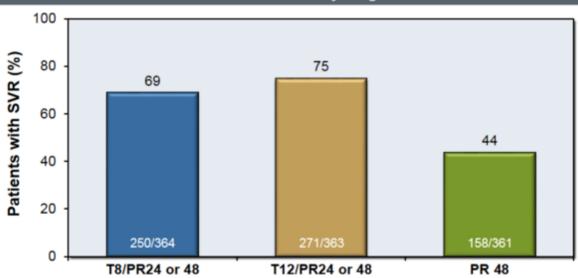
Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE Study: Treatment Regimens





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

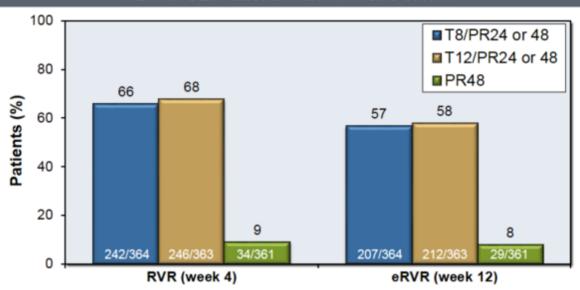
ADVANCE: SVR24 by Regimen





Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE Study: RVR and eRVR Rates

ADVANCE: Patients with RVR and eRVR

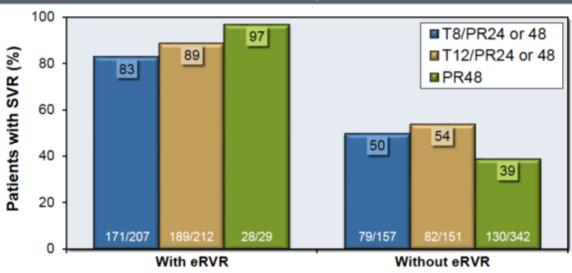


T = Telaprevir; PR = Peginterferon + Ribavirin; RVR = rapid virologic response; eRVR = extended rapid virologic response



Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE Study: Results According to eRVR

ADVANCE: SVR24 by eRVR Status

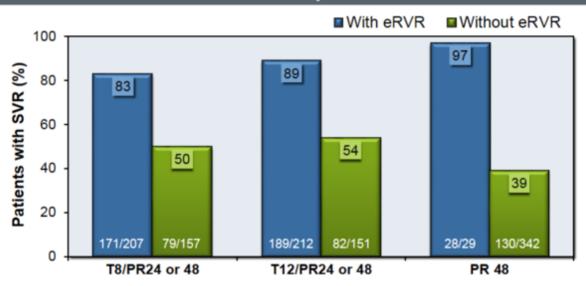


T = Telaprevir; PR= Peginterferon + Ribavirin; SVR = Sustained Virologic Response eRVR = extended rapid virologic response (undetectable HCV RNA at weeks 4 and 12)



Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE Study: Results According to eRVR

ADVANCE: SVR24 by eRVR Status

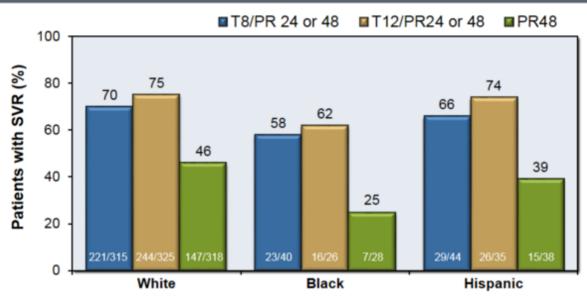


SVR = Sustained Virologic Response; T = Telaprevir; PR = Peginterferon + Ribavirin; eRVR = extended rapid virologic response (undetectable HCV RNA at weeks 4 and 12)



Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE Study: Results According to Race

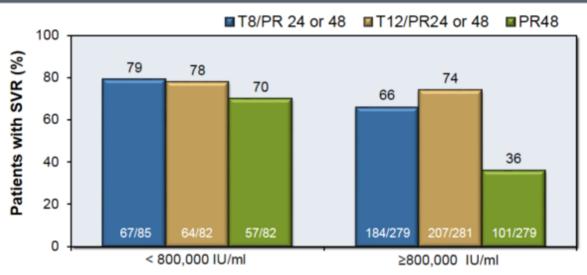
ADVANCE: SVR24 by Race





Telaprevir for Treatment-Naïve HCV Genotype 1 ADVANCE Study: Results by Baseline HCV RNA

ADVANCE: SVR24 by Baseline HCV RNA Level



Baseline HCV RNA Level

