

Telaprevir in Treatment Experienced GT-1 REALIZE (Study 216)

Zeuzem S, et al. N Engl J Med. 2011;364:2417-28.

Telaprevir for Treatment-Experienced HCV Genotype 1

REALIZE Study: Study Design

REALIZE: Study Features

- Phase 3 trial
- Randomized, double-blind, placebo-controlled
- Eligible if 18 to 70 years of age
- All with genotype 1 chronic HCV infection
- Lack of SVR with prior peginterferon + ribavirin treatment
- N = 663 enrolled
- Setting: 100 international sites (most in Europe and US)
- Randomized to one of 3 arms (2:2:1 ratio)

Drug Dosing

Telaprevir = 750 mg q8h

Peginterferon alfa-2a = 180 µg weekly

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

Telaprevir for Treatment-Experienced HCV Genotype 1 REALIZE Study: Definitions for Prior Response

- **No Response:** Reduction of less than $2 \log_{10}$ in HCV RNA after 12 weeks of therapy
- **Partial Response:** Reduction of $2 \log_{10}$ or more in HCV RNA after 12 weeks of therapy, but with detectable HCV RNA
- **Relapse:** undetectable HCV RNA at the end of a previous course of therapy but HCV RNA positivity thereafter

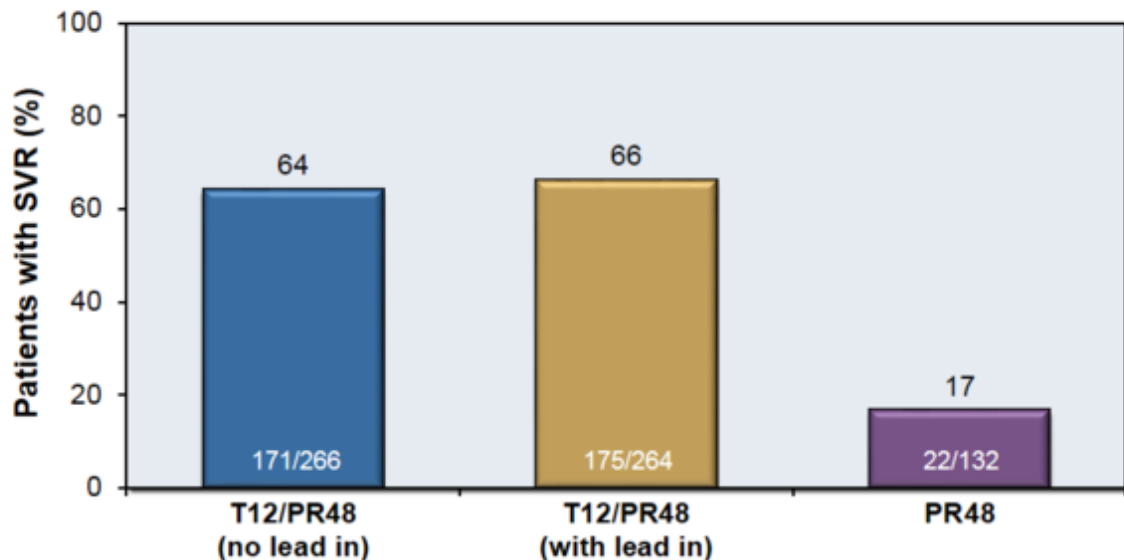
Telaprevir for Treatment-Experienced HCV Genotype 1

REALIZE: Treatment Regimens



Telaprevir for Treatment-Experienced HCV Genotype 1 REALIZE Study: Results

REALIZE: SVR24 by Regimen



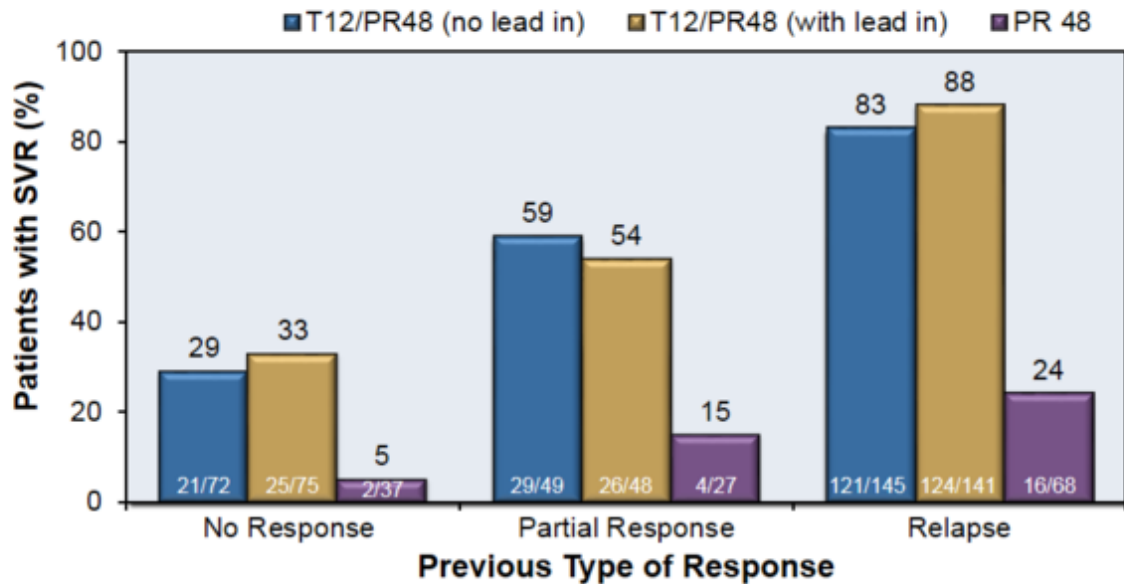
SVR = Sustained Virologic Response; T = Telaprevir; PR = Peginterferon + Ribavirin

Source: Zeuzem S, et al. *N Engl J Med.* 2011;364:2417-28.

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REALIZE: Results Based on Prior History

REALIZE: SVR24 by Prior Response



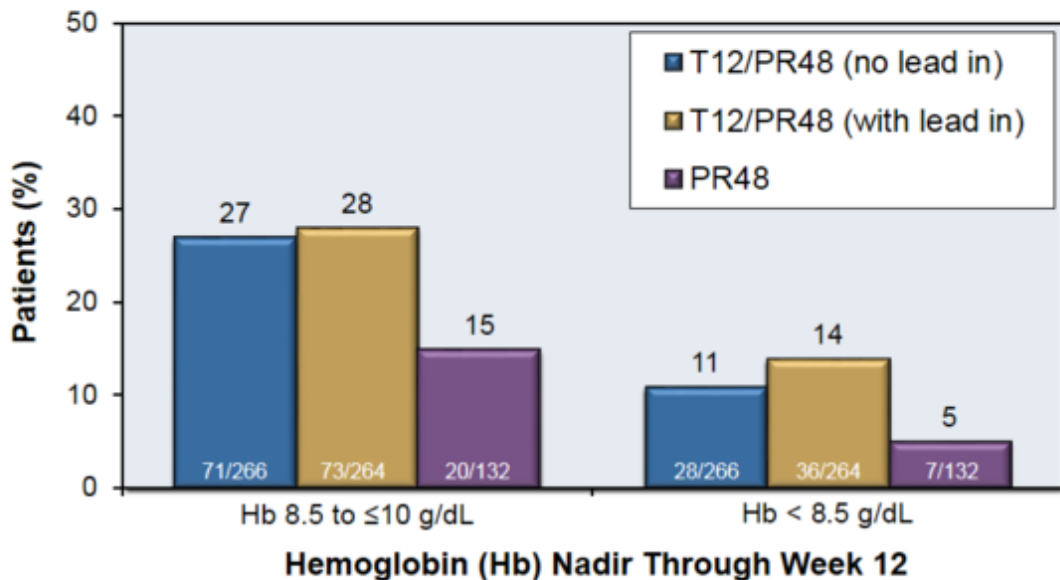
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REALIZE: Adverse Effects

REALIZE: Anemia



T = Telaprevir; P = Peginterferon + Ribavirin

Source: Zeuzem S, et al. *N Engl J Med.* 2011;364:2417-28.

Telaprevir for Treatment-Experienced HCV Genotype 1 REALIZE Study: Conclusions

Conclusions: “Telaprevir combined with peginterferon plus ribavirin significantly improved rates of sustained virologic response in patients with previously treated HCV infection, regardless of whether there was a lead-in phase.”