Treatment Naïve

Telaprevir in Treatment Naïve GT-1
ILLUMINATE (Study 111)

Sherman KE, et. al. N Engl J Med. 2011;365:1014-24.

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

ILLUMINATE: Study Features

- Randomized, open label, Phase 3 trial
- Genotype 1 HCV and treatment naïve, with or without cirrhosis
- N = 540 enrolled
- RVR = HCV RNA undetectable at week 4
- eRVR = HCV RNA undetectable at weeks 4 & 12
- Erythroid stimulating agents not allowed
- All received telaprevir x 12 weeks
- Patients with eRVR randomized to PR for 24 or 48 weeks
- Patients without eRVR received PR x 48 weeks

Drug Dosing

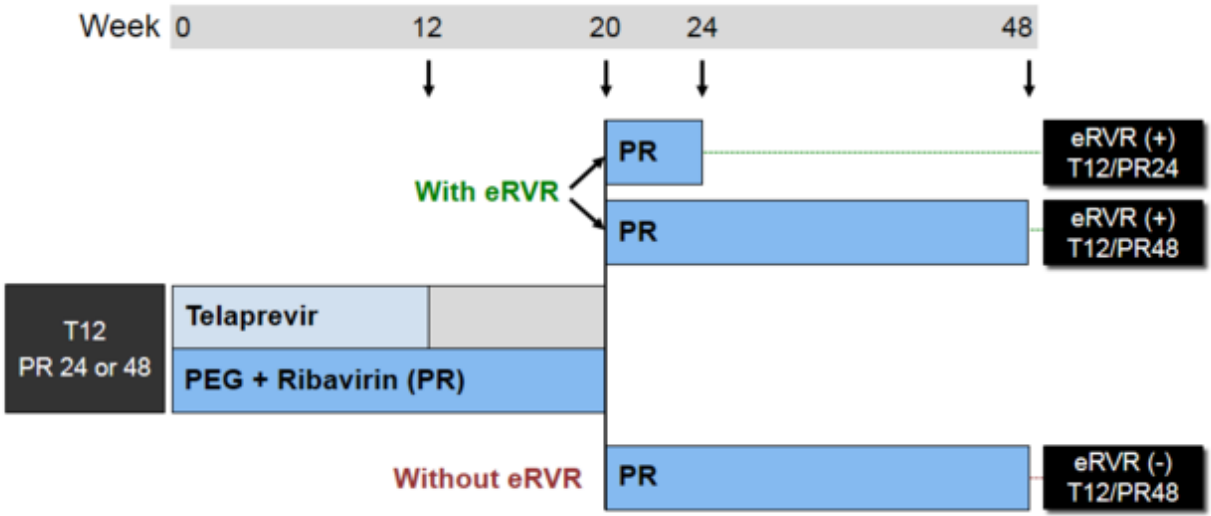
Telaprevir = 750 mg every 8 hours

Peginterferon alfa-2a = 180 µg per week

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

Source: Sherman KE, et. al. N Engl J Med. 2011;365:1014-24.

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

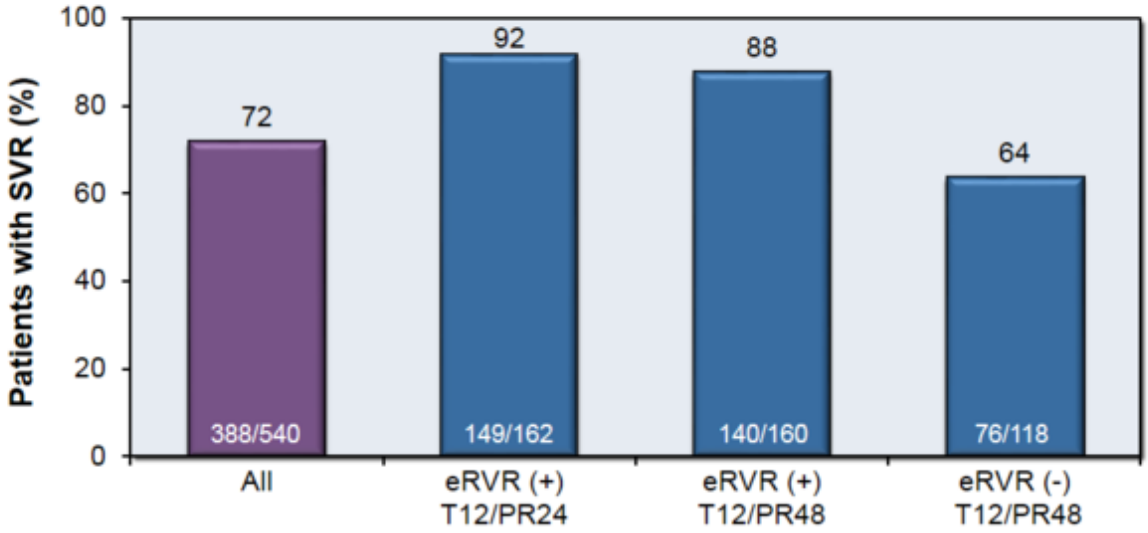


T = Telaprevir
PR = Peginterferon + Ribavirin
eRVR = extended rapid virologic response (undetectable HCV RNA at weeks 4 and 12)

Source: Sherman KE, et. al. N Engl J Med. 2011;365:1014-24.

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

ILLUMINATE: SVR 24 by Regimen



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

Source: Sherman KE, et. al. N Engl J Med. 2011;365:1014-24.

Telaprevir for Treatment-Naïve HCV Genotype 1 ILLUMINATE Study: Key Findings

- 24 weeks of Peg-IFN non-inferior to 48 weeks in patients with eRVR
- Overall SVR 72%
- SVR in 60% of blacks
- SVR of 63% in patients with cirrhosis
- 65% of patients had eRVR
- 88-92% of those who achieved eRVR achieved SVR
- 7% stopped treatment early due to virologic failure
- 17% stopped early due to fatigue or anemia

Source: Sherman KE, et. al. N Engl J Med. 2011;365:1014-24.

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

Conclusions: "In this study, among patients with chronic HCV infection who had not received treatment previously, a regimen of peginterferon–ribavirin for 24 weeks, with telaprevir for the first 12 weeks, was noninferior to the same regimen for 48 weeks in patients with undetectable HCV RNA at weeks 4 and 12, with an extended rapid virologic response achieved in nearly two thirds of patients."

Source: Sherman KE, et. al. N Engl J Med. 2011;365:1014-24.