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Treatment of hepatitis C genotype 1 patients with severe fibrosis or compensated cirrhosis: the telaprevir early access program in patients from Romania

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Background

HEP3002 is an ongoing, open-label, early access program of telaprevir in 16 countries, for patients with genotype 1 hepatitis C with severe fibrosis or compensated cirrhosis. This interim analysis is of 16 week data from the 209 patients from Romania.

Methods

Patients were treated with telaprevir in combination with peginterferon alfa and ribavirin (PR) for 12 weeks, followed by PR for 12 or 36 weeks. Severe fibrosis/cirrhosis was defined by liver biopsy (Metavir F3-4 or Ishak 3-6) or non-invasive tests. Platelet count >90,000/cmm was required at entry. HCV RNA was evaluated at baseline and Weeks 4 and 12 of treatment. Virological response was defined as serum HCV RNA not detected, for the Intent to Treat (ITT) population.

Results

Mean age was 52 years; 47% were male and 100% Caucasian, 59% had HCV RNA levels ≥800,000 IU/mL, 58%/42% had severe fibrosis/cirrhosis, 2% had genotype 1a, 14% were treatment naïve, 75% prior relapsers, 3% prior partial responders, 7% prior null responders and 1% had prior viral breakthrough. HCV RNA responses (percent undetectable) at weeks 4 and 12 (ITT analysis) are shown in Table 1.

Table 1

Percent HCV RNA not detected	Week 4 (RVR)	Week 4+12 (eRVR)	Week 12
Treatment-naïve (n=30)	73%	70%	93%
Prior relapser (n=156)	85%	81%	94%
Prior partial responder (n=6)	100%	83%	83%
Prior null responder (n=15)	80%	73%	80%
Overall[a] (n=209)	83%	79%	92%

[a]includes 2 patients with prior virological break-through, not in four categories above

Nine patients (4%) discontinued TVR due to adverse events, including six (3%) for rash and one (<1%) for anaemia. The rate of serious adverse events was 9% and no patients died during the study.

Conclusion

In this telaprevir early access program for hard-to-cure patients with severe fibrosis or compensated cirrhosis, early on-treatment virological responses are encouraging. Rates of discontinuation of telaprevir for adverse events were similar to Phase 3 trials.

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