Early Clearing of HCV RNA in HCV Genotype 1 Treatment-naive Patients Treated with Telaprevir, Peginterferon and Ribavirin: Pooled Analysis of the Phase 3 Trials ADVANCE and ILLUMINATE

KE Sherman, GT Emerson, SM Jacobson, AM Boulware, DR Neumann, I Benjamins, N Adda, RS Kaufman, CI Wright, and S Zuzuserri

Address correspondence to: Kenneth E Sherman, MD, PhD, Division of Digestive Diseases, University of Cincinnati College of Medicine, Cincinnati, OH 45267; E-mail: KESherman@uc.edu

ABSTRACT

Background: Influenza-like Illness

INTRODUCTION

METHODS

RESULTS

SUMMARY AND CONCLUSIONS

Patient Population

Efficacy Assessments

Safety Assessments

TAB 1: Baseline Characteristics and Demographics

Table 3: Most Common Adverse Events in Greater than 20% of Patients in the Overall EtaRVR Cohort

Author Disclosures

ACKNOWLEDGMENTS

Figure 1B: Study Design of ILLUMINATE Trials

Figure 18: Study Design of ILLUMINATE Trials

Figure 2: Patients with Undetectable HCV RNA over Time

Figure 3: Patients with eRVR According to Week 1, Week 2, or Week 4 HCV RNA

Figure 4: Patients with Undetectable HCV RNA at Week 1, Week 2, Week 4, and Week 42

Figure 5: Patients with Undetectable HCV RNA at Week 42

Table 2: Rates of On-treatment Failure and Relapse: Patients who have SVR early in treatment phase were 7% and 4% for T12PR and PR, respectively.

Table 2: Rates of On-treatment Failure and Relapse: Patients who have undetectable HCV RNA at Week 1, Week 2, Week 4, and Week 42

SUMMARY AND CONCLUSIONS

• More patients were undetectable for HCV RNA at early timepoints when treated with a telaprevir-based regimen.

- 4%, 32%, and 20% of T12PR patients had first undetectable HCV RNA at Week 1, Week 2, and Week 4, respectively.

- 2%, 2%, and 3% of patients treated with peginterferon alfalfa-2a/ribavirin alone had first undetectable HCV RNA at Week 1, Week 2, and Week 4, respectively.

- Patients treated with a telaprevir-based regimen, who had early HCV RNA undetectability, had higher sustained viral response rates – 90% of patients, with undetectable HCV RNA at Week 1, achieved a sustained viral response rate compared to 85% and 77% in Week 2 and Week 4 first undetectable HCV RNA patients.

- Regardless of treatment regimen, patients with early HCV RNA undetectability had higher sustained viral response rates, however, as stated above, fewer patients treated with peginterferon alfalfa-2a/ribavirin alone had undetectable HCV RNA at early timepoints compared to patients who received telaprevir-based regimen.

- A majority of patients treated with peginterferon alfalfa-2a/ribavirin alone received 24 weeks of total treatment while all patients treated with peginterferon alfalfa-2a/ribavirin alone received 48 weeks of total treatment.

- There were low discontinuation rates of all study drugs due to rash and anemia events during the telaprevir treatment phase with overall discontinuation rates due to adverse events of 7% and 4% in T12PR and peginterferon alfalfa-2a/ribavirin patients respectively.


3. Hepatol. 2007;45:149A.


5. Gastroenterology. 2009, 137:520A.


7. Interim analysis data reported in T12PR patients, where patients were pruritic, nausea, and rash on hold, Table 3.

8. Discontinuation rates of all study drugs including 1% and 2% of T12PR and 2% and 3% of PR patients due to rash and anemia events, respectively.

9. During the overall treatment phase, 1% and 2% of T12PR patients discontinued study drugs in 1% and 2% and 3% of PR patients due to rash and anemia events, respectively.

References

ACKNOWLEDGMENTS

Presented at the 18th Conference on Retroviruses and Opportunistic Infections (CROI), Boston, MA, USA; February 27 - March 2, 2011. Supported by Bristol-Myers Squibb Inc. and Willy Pharmaceuticals Incorporated.