STUDY DESIGN

The 3 phase 2 clinical trials included in the analysis were A-VICTOR (NCT01648297) and M-13-013 (NCT01319194). Both were multicenter, open-label, 12-week M14-123-030 and up to 24-week studies. M-13-013 was conducted at 8 sites in the United States, and A-VICTOR was conducted at 92 sites in 9 countries, including the United States. – Prior to patient enrollment in M-13-013, a double-blind washout study was performed to evaluate the effect of ABT-450/ombitasvir and dapivirine in 24 healthy volunteers taking chronic HCV monoinfection and 24 healthy volunteers taking ABT-450/omnitasv/ribavirin/sulfoximine. In addition, volunteers completed comprehensive spondomyalgia that evaluated episodic wrist syndrome (Subjective Opiate withdrawal Scale) and the desire for drugs (Drug Dependence Treatment Scale). The study was conducted at 26 sites in 6 countries, and the majority of the clinical sites were for drug groups. – No significant interactions with the regimen were identified.

METHODS

• Patients in all studies received ABT-450 and icosaprevir once daily at doses of 1000 mg/100 mg and 125 mg, respectively and dasabuvir twice daily at 75 mg.

CAT-13/060: Results of the SVRB12-13-005 study were consistent with those observed in the SVRB12-13-003 study. No patients developed a resistant strain of HCV. – At week 24, patients who achieved an SVR12 had clearance of HCV RNA in over 95% of the cases. – During the treatment period, patients experienced an SAE (acute myeloid leukemia, n = 1; cerebrovascular accident and sarcoma, n = 1) and no patients required a dose adjustment of OS during the treatment period.

Table 2. Common Treatment-emergent Adverse Events Occurring in 2% or More of Patients

PATIENTS

• Men and women 18–70 years of age with chronic HCV infection (HCV RNA levels >10000 copies/mL) or with or without cirrhosis were included in this analysis; patients could have been treatment-naive or treatment experienced with prior pegylated interferon (pegIFN)/ribavirin (RBV) therapy.

EFFICACY ASSESSMENT

• SVRB12 was defined as failure to suppress HCV RNA by week 5, viral breakthrough while on treatment, or post-treatment relapse.

SAFETY ASSESSMENTS

• Information on adverse events (AEs) was collected at baseline and at each study visit from the first time the study drug was administered until 30 days after the last dose; serious AEs (SAEs) were monitored through the study.

STATISTICAL ANALYSES

• All patients receiving OS who achieved SVR12 and those with HCV GT1a and GT1b infection.

RESULTS

• Across the 6 clinical trials, 2292 patients were randomized and received at least 1 dose of study drug; 16 patients were excluded because of virologic failure: 10 patients with stable OST, 4 patients with HCV GT1a and GT1b infection.

EFFICACY

• The incidence of AEs and laboratory abnormalities was summarized.

Figure 1. SVRB12 Rates in Patients Receiving OS with HCV GT1a and GT1b Infection

Table 1. Baseline Demographics and Disease Characteristics (ITT Population)

LABORATORY ABNORMALITIES: AEs of SPECIAL INTEREST

• Grade 3 bilirubin elevation occurred in 1 patient (1.6%) (Table 3).

• There were no grade 2 or higher elevations in alanine transaminase, aspartate aminotransferase, or alkaline phosphatase.

• Grade 2 (10–20×ULN) and grade 3 (30–50×ULN) or higher were reported in 6 patients (24.3%) and 2 patients (8.3%), respectively.

ACKNOWLEDGEMENTS

The design, study conduct, analysis, and financial support of the clinical trials were provided by AbbVie. AbbVie participated in the presentation of data, review, and approval of the manuscript. All authors had access to all relevant data. Roderick Sayce of Complete Publications, LLC, and Susan Hogan provided medical writing support. This presentation contains information on the investigational products ABT-450, icosaprevir (ABT-267), and dasabuvir (ABT-333).

REFERENCES