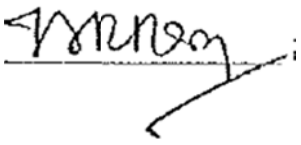
Statistical analysis

The efficacy analysis was based on 288 enrolled patients, while relapse analysis included 283 patients. T-test was used to determine the p-values for means (standard deviation) while Wilcoxon test was used to determine the p-values for medians (interquartile range) for continuous variables. For categorical variables, chi-squared test was used to determine p-values, and frequencies were summarized as n (percent). These methods were used for summarizing baseline characteristics and for completing preliminary efficacy and safety analyses.

Multi-variable logistic regression analysis was used to evaluate the relationships between treatment duration and SVR, baseline factors and SVR, and baseline factors and relapse. This analysis was used to compute p-values and odds ratios, their 95% confidence limits, and p-values. The model for treatment duration was adjusted for several prognostic factors identified by preliminary efficacy analysis including age, sex, and liver stiffness. This model evaluated genotype 3 only, as this was the only genotype where treatment duration varied. Models exploring outcomes and baseline factors excluded genotype 2 cases, as broad conclusions from pooled analysis may not be represented in the small sample size of patients with this genotype (n = 4). As treatment duration was not found to be a significant factor for SVR, it was excluded from subsequent models. The final outcome models were adjusted for age, sex, liver stiffness, genotype, platelet levels ≥150000/mm^3, albumin levels ≥ 3.5 g/dL, and pre-treatment HCV RNA ≥800000 IU/mL. All analyses were conducted using SAS v9.4 (Cary, NC).



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