RESULTS (cont’d)

Methods: The objectives of this open-label, multiple-ascending dose design were to evaluate the antiviral activity, safety, tolerability, and pharmacokinetics of BMS-824393 in treatment-naive patients with genotype 1 chronic HCV. Men or women, 18 to 60 years of age with HCV RNA ≥20,000 IU/mL with necroinflammatory liver disease received either 1, 10, 50, or 100 mg of BMS-824393 for 3 days (10 subjects [7 G1a and 3 G1b] per dose group). The median decline in HCV RNA levels from baseline was measured with the Abbott RealTime HCV RNA Test. LOQ = 12 IU/mL. Pharmacokinetic parameters were derived from the plasma concentration-time data.

Conclusions: BMS-824393 is BMS’s second NS5A Inhibitor that produces a rapid and robust decline in HCV RNA following multiple doses in patients chronically infected with HCV genotype 1a or 1b. BMS-824393 was well-tolerated following multiple doses of up to 100 mg and has a pharmacokinetic profile that supports once-daily dosing. These results provide further confirmation of the value of inhibiting NS5A-mediated HCV replication in the treatment of HCV. Further studies are planned to confirm the role of NS5A inhibition in future HCV therapies.

Background and Objectives

• NS5A is a multifunctional protein that plays a central role in replication of HCV, making it an attractive target for therapeutic intervention.

• BMS-824393 is a second NS5A Inhibitor in development by BMS, a potent and highly selective inhibitor of HCV NS5A, with in vitro potency against genotypes 1a and 2a.

• BMS-824393 was well-tolerated in single and multiple doses in healthy subjects.

• BMS-824393 has demonstrated a pharmacokinetic profile supportive of once-daily dosing.

The objectives of the current study were to evaluate the antiviral activity, pharmacokinetics, safety, and tolerability of BMS-824393 in subjects chronically infected with HCV genotype 1.

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