SYNOPSIS

Final Clinical Study Report for Study AI463137

TITLE OF STUDY: A Comparative Study of the Antiviral Efficacy and Safety of Entecavir Plus Tenofovir Versus Adefovir Added to Continuing Lamivudine in Adults with Lamivudine Resistant Chronic Hepatitis B Virus Infection

PURPOSE: This study was designed to investigate whether combination therapy with entecavir (ETV) 1 mg plus tenofovir (TDF) 300 mg had superior antiviral activity compared with adefovir (ADV) 10 mg added to continuing lamivudine (LVD) 100 mg therapy in hepatitis B e antigen (HBeAg)-positive or -negative chronic hepatitis B virus (HBV) subjects who exhibited genotypic resistance to LVD. Following a review of business priorities, Bristol-Myers Squibb Company decided to terminate this study at an early stage. This was a strategic decision, not based on clinical or safety concerns.

NUMBER OF SUBJECTS: Four subjects were enrolled, and 2 subjects were randomized and treated with the study drugs (1 in each treatment group).

DISPOSITION, DEMOGRAPHICS AND OTHER PERTINENT BASELINE CHARACTERISTICS:

- Subject [redacted] was treated with oral ETV (1 mg/day) plus TDF (300 mg/day) combination therapy
- Subject [redacted] was treated with oral ADV (10 mg/day) plus continuing LVD (100 mg/day).

SUMMARY OF SAFETY RESULTS:

Neither subject died, had serious adverse events, or discontinued the study drugs due to adverse events (AEs) or laboratory abnormalities. Both subjects had AEs:

- Subject [redacted] (ETV plus TDF) - Day 3 - continuing - moderate (Grade 2) acid stomach considered probably related to the study drugs by the investigator
- Subject [redacted] (ADV plus continuing LVD) - Days 2 to 17 - mild (Grade 1) fatigue considered not likely related to the study drugs by the investigator, and Days 29 to 51 - moderate (Grade 2) exacerbation of hepatitis considered probably related to the study drugs by the investigator.

CONCLUSIONS: Due to the small sample size, no conclusions can be drawn from these data.

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