

SYNOPSIS

Final Clinical Study Report for Study MB102020

TITLE OF STUDY: Characterization of the Kinetics of Renal Glucose Reabsorption in Response to Dapagliflozin in Healthy Subjects and in Subjects with Type 2 Diabetes Mellitus.

PURPOSE: The purpose of this study was to evaluate and compare the renal glucosuric effect of dapagliflozin as characterized by changes in the glucose transport maximum (Tm_G)/Splay of the glucose titration curve after multi-dose administration of dapagliflozin in healthy subjects and in subjects with Type 2 diabetes mellitus (T2DM). This study was terminated due to serious noncompliance at the clinical site after treating 1 subject and prior to completing enrollment.

NUMBER OF SUBJECTS: Twelve (12) subjects with T2DM and 12 healthy subjects were planned and 15 subjects were enrolled in the study. Only one subject was treated and did not complete the protocol-specified study assessments.

DISPOSITION, DEMOGRAPHICS AND OTHER PERTINENT BASELINE CHARACTERISTICS:

SUMMARY OF SAFETY RESULTS: In the one subject treated in this study, no adverse events (AEs) or laboratory values that met marked laboratory abnormality (MA) criteria were observed.

CONCLUSIONS:

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DATE OF REPORT: 02-Sep-2010