**Protocol MB130002**: A randomized, double-blind, placebo-controlled, parallel-group, multiple dose study to evaluate the safety, pharmacokinetics and pharmacodynamic effects of BMS-986036 in obese adults with type-2 diabetes

**Amendment Number 04**

**Site Number: All**

This protocol amendment contains information that is confidential and proprietary to Bristol-Myers Squibb (BMS).

*This amendment must be maintained with the referenced protocol.*
Amendment Rationale:
The purpose of this amendment is to support additional safety follow up for subjects showing a positive immunogenicity trend during 6 months following the Day 126 Discharge visit. This amendment should be Ethics Committee-reviewed and approved prior to implementation. This revision applies to all enrolled subjects.

Changes to the Protocol:
1. Synopsis, Duration of the Study. Text is added at the end: “Follow up to 12 months post Discharge may be requested to support additional immunogenicity testing.”
2. Section 1.5.1 Risk Mitigation Strategy, Immunogenicity, 4th paragraph; and Section 5.8 Immunogenicity, second paragraph. Text is added at the end of the paragraph: “Subjects showing a positive immunogenicity trend at that 6 months post study discharge will be asked to attend follow up for up to 6 additional months until antibody levels resolve or demonstrate a consistent decreasing trend.”

Please maintain a copy of this amendment with your protocol. Please provide a copy to your Investigational Review Board / Ethics Committee, unless agreed otherwise with BMS.
AMENDMENT ACKNOWLEDGMENT

I have read this Amendment and agree that it contains all necessary details for carrying out the changes described. I understand that it must be reviewed by the Institutional Review Board or Independent Ethics Committee overseeing the conduct of the study and approved or given favorable opinion by all necessary Health Authorities before implementation unless to eliminate an immediate hazard to subjects.

If this Amendment substantially alters the study design or increases potential risk to subjects, the consent form will be revised and submitted to the Institutional Review Board/Independent Ethics Committee for approval/positive opinion. I will use the new consent form for any new subjects prior to enrollment, and for subjects currently enrolled in the study if they are affected by the Amendment.

________________________________________________________________________
Investigator's printed name and signature Date

________________________________________________________________________
Medical Monitor/Study Director Date
(If required by applicable regulations and guidelines.)

Protocol Number: MB130002
Site Number: 
Amendment Number: 04