

## BMS INFORMED CONSENT FORM (ICF) ADDENDUM

APPROVED  
Jun 13, 2016  
WIRB®

**TITLE:** A Multi-arm, Phase 3, Randomized, Placebo Controlled, Double Blind Clinical Trial to Investigate the Efficacy and Safety of BMS-663068 in Heavily Treatment Experienced Subjects Infected with Multi-drug Resistant HIV-1

**PROTOCOL NO.:** A1438047  
WIRB® Protocol #20150142

**SPONSOR:** Bristol-Myers Squibb

**INVESTIGATOR:** Pablo Tebas, MD  
502 Johnson Pavilion  
Philadelphia, Pennsylvania 19104  
United States

**STUDY-RELATED  
PHONE NUMBER(S):** Pablo Tebas, MD  
215-349-8092  
215-662-6059 (24-hour number)

**STUDY-  
COORDINATOR(S):** Aleshia Thomas, RN, BSN  
Joseph Quinn, RN, BSN

**SITE NUMBER:** 215-349-8092

This document provides you with new and additional information about this clinical trial.

All parts of the informed consent that you have signed before remain valid, as does your consent to it, except any that are specifically revised by this document.

### New/Revised Information about this Clinical Trial

#### Risks / Possible Adverse Drug Reactions

Based on what the sponsor and other researchers have learned up to this point about The BMS Attachment Inhibitor (BMS-663068), the following adverse drug reactions are known:

BMS-663068: nausea, headache, vomiting, elevated level of hepatic laboratory parameters, itching, rash, abdominal pain, bloodshot eyes, dizziness, backache, tingling, swelling of the upper lip and mouth, throat tightness, lightheadedness, dry mouth, tiredness, sweating, weakness, sore throat or mouth, muscle ache or burning, bruising, sinus congestion, eye irritation, heart palpitation, ear pain, constipation, diarrhea, toothache, nervousness, cold symptoms, gas and belching, increased frequency of urination, burning with urination and changes in the electrical activity of the heart.

Four serious conditions were reported in patients who received experimental treatment with the BMS Attachment Inhibitor at any dose: viral meningitis (swelling of protective layer of brain caused by virus), Mobitz type I second degree, atrioventricular block (a type of heart rhythm defect), death due to pulmonary embolism (clot in blood vessel of lung), and anaphylaxis (an extreme allergic reaction).

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Recent routine testing on BMS-663068 has demonstrated the potential for trace amounts of an impurity (BMT-218946) to form in the drug which could cause an allergic reaction in patients taking this medicine. The impurity includes a chemical structure known as a beta-lactam ring; a structure that is found in many commonly prescribed antibiotics including penicillin. Patients with a prior allergic reaction to penicillin or other beta-lactam-containing antibiotics may or may not be at risk for a serious allergic reaction when taking BMS-663068.

One patient, with no previous drug allergy, who participated in one of the BMS-663068 studies developed anaphylaxis (severe allergic reaction) after 5 days of taking BMS-663068. The patient had rash and swelling of the throat (pharyngeal edema) accompanied by mild shortness of breath. The patient was stable throughout the event and the symptoms resolved with treatment after several hours.

If you experience symptoms of a serious allergic reaction, including any of the following:

- Severe rash, including rash with fever, peeling of skin, or welts (urticaria);
- Swelling of the face, mouth, or throat (angioedema);
- Difficulty breathing, wheezing, or chest tightness (bronchospasm);
- Feeling dizzy or that you may pass out

Please seek immediate emergency medical care and contact your study doctor.

### Questions/Information

If you or your representative(s) have any questions regarding the information above, you should contact your study doctor at the telephone number on page one of this form.

### SIGNATURE

- I have read the information presented in this addendum of the Informed Consent Form. I have been given the opportunity to ask questions and all my questions have been answered to my satisfaction.
- I confirm that I have received a Subject Alert Card providing the contact details of the study doctor. I agree to carry this card with me at all times.
- I shall receive a signed and dated copy of this Informed Consent Addendum.
- **I FREELY ACCEPT TO CONTINUE MY PARTICIPATION IN THIS STUDY**

To be signed simultaneously, (i.e. same date), by all parties:

Distribution: original for study doctor, copy to Subject /Patient

\_\_\_\_\_  
Print Name (Last Name, First Name)  
of Subject / Patient

\_\_\_\_\_  
Date  
(to be entered by Subject)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name of person obtaining the  
consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

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If the participant is unable to read the ICF, then the signature of an impartial witness is needed.

The information in this informed consent addendum document was read to the study participant or his/her legally acceptable representative. I believe he/she understands what was read and explained and is freely agreeing to participate in the study. The subject or representative has signed or made his/her mark on the signature line above.

\_\_\_\_\_  
Name of Impartial Witness

\_\_\_\_\_  
Date  
(to be entered by witness)

\_\_\_\_\_  
Signature

At any given time an incapacitated individual may explicitly refuse to participate in or request to be withdrawn from the clinical trial. The study doctor must respect the request.