NRG ONCOLOGY

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April 6, 2020

Dear Investigator:

You are receiving this letter because you have participated in and are currently treating a patient on **NRG-GY018**, "**A PHASE III RANDOMIZED, PLACEBO-CONTROLLED STUDY OF PEMBROLIZUMAB (MK-3475, NSC #776864) IN ADDITION TO PACLITAXEL AND CARBOPLATIN FOR MEASURABLE STAGE III OR IVA, STAGE IVB OR RECURRENT ENDOMETRIAL CANCER."**

The purpose of this letter is to inform you that out of an abundance of caution (to reduce patient visits to infusion centers) during the COVID-19 pandemic it has been decided to unblind patients who are now on maintenance therapy as well as subsequent patients as they are entering the maintenance therapy portion of the trial. Please follow the instructions for unblinding in Section 5.2 (inserted below) prior to next planned maintenance cycle for all of your patients. Patients receiving pembrolizumab may proceed with treatment per study. Patients receiving placebo will enter follow up. To ensure the integrity of the trial, all patients should continue radiologic tumor measurements and patient reported outcomes as planned per Tables 4.2 and 4.3.

Section 5.2:
Emergency Unblinding Procedure & Unblinding at the time of disease progression for dMMR/MSI-H patients
The decision to break the unblinding code must be based on a serious adverse event unexpected for the study drug and related to the study drug or extraordinary clinical circumstance for which knowledge of drug assignment will affect clinical judgment. In addition, unblinding will be permitted for dMMR/MSI-H patients at the time of documented disease progression.

The NRG Oncology SDMC maintains an unblinding service that is in operation 24 hours a day, seven days a week. When unblinding is required, the institution representative (PI or CRA) must telephone the NRG Oncology SDMC office at **412-624-2666** and state that they wish to unblind a patient's study drug assignment (*see below for additional instructions for unblinding due to the COVID-19 situation). The institution representative will be referred to the Unblinding Administrator. In order to unblind the study drug assignment, the Unblinding Administrator will ask the institution representative to identify the protocol number, the patient ID number, the patient initials (LFM), and the reason for the unblinding request. After this information has been obtained and the indication for unblinding is confirmed, the site representative will be notified immediately of the patient's treatment assignment and a computer record will be created identifying the patient as having been unblinded. The institution is still responsible for providing continued follow-up for patients whose treatment assignment has been unblinded on the same schedule as indicated in the study protocol.

*Site representative must also email Mimi Passarello (passarelloM@nrgoncology.org)

On behalf of NRG Oncology, the three Group Chairs, and the National Cancer Institute, we want to thank you and your patient for participating in this important clinical trial.

Sincerely,

Robert S. Mannel, MD
NRG Oncology Group Chair