Alliance for Clinical Trials in Oncology
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July 02, 2021

Dear Alliance A081801 Physician Participant:

This letter is to provide you with information regarding Alliance A081801, "Integration of immunotherapy into adjuvant therapy for resected NSCLC: ALCHEMIST chemo-IO (ACCIO)". As presented at the American Society of Clinical Oncology conference in June 2021, the IMpower010 trial (adjuvant atezolizumab versus observation after surgical resection and adjuvant chemotherapy for non-small cell lung cancer [NSCLC]) met the primary endpoint of disease-free survival in individuals with stage II/IIB NSCLC and PD-L1 ≥1%. In this trial, patients were enrolled after surgical resection of stage IB-IIIA NSCLC with negative margins and standard of care adjuvant chemotherapy, and then were randomized to either atezolizumab or observation. The statistical hierarchy defined an initial analysis of those with stage II-IIIA and PD-L1 ≥1%, which was reported as having met the endpoint of statistical significance with longer disease-free survival. The analysis of all stage II-IIIA NSCLC including all PD-L1 expression was also reported as positive for increase in disease-free survival.

Although IMpower010 yielded a positive disease-free survival result for stage II/IIIA NSCLC, further data from the trial is being analyzed and, at present, has not yet been published. Additionally, the FDA has not confirmed the data and/or approved atezolizumab in this patient population. Because no change in the current adjuvant treatment landscape for NSCLC has occurred, we believe that accrual to A081801 can continue with a brief amendment to the informed consent and background section of the protocol to reflect these new developments. A draft of this patient letter accompanies this memorandum. The following actions are now required:

1. Upon receipt of this notice, physicians should discuss the atezolizumab study results with all patients enrolled in this trial. To facilitate this discussion, a sample patient letter is available on the Alliance A081801 study page on the member side of the Alliance and CTSU web sites. Documentation of the discussion with the patient should be kept in the patient's medical record.
2. Please note that it is not necessary to obtain IRB approval before notifying patients. The NCI CIRB is the IRB of Record for this trial, therefore, the Alliance will inform the NCI CIRB of this notification and provide copies of the physician and patient letters to the NCI CIRB.

Questions regarding this matter can be directed to Dr. Jacob Sands at Jacob_sands@dfci.harvard.edu
Questions regarding this notice may be directed to Ms. Colleen Watt at cboyle@uchicago.edu.

We greatly appreciate your support of this important clinical trial and the work of the Alliance for Clinical Trials in Oncology.

Sincerely,

Jacob Sands, MD
Alliance A081801 Study Chair