ID UYAR 25680 IIT MERCK: Phase II Pembrolizumab/Carbo/Taxol in Epithelial Ovary Cancer

NCT02766582

Date: 3/15/23

Statistical Analysis Plan

Progression-free survival (PFS) is defined as the date of completion of primary therapy to the date of the first clinical, biochemical, or radiological evidence of progression or death due to any cause. PFS will be censored at the last assessment of disease progression for living patients. The efficacy parameters of survival will be analyzed using Kaplan-Meier curves stratified by the group where the groups are compared using a log-rank sum test. Using Pass 12, the primary comparison is the PFS of the treated sample compared to historical controls. We planned to accrue patients over 3 years with a follow-up of at least 18 months. The calculation was done with the sample size calculation based on the work of Lakatos. 18 The comparison is a two-sided log-rank sum test, at an alpha of 0.05. Using the study by Katsumata the median survival time was an estimated 18 months for the conventional carboplatin-paclitaxel chemotherapy regimen for those with >1cm remaining post-surgery. Realistically an increase of median PFS by 6 months would have indicated efficacy but with a treatment sample of 30 and the control sample from Katsumata of 168, we would have at least 80% power to detect at least an increase for 1.5 years to ~3 years, an optimistic outcome.

A waterfall plot illustrates the maximum percent change in tumor measurement per RECIST from baseline. Continuous variables are summarized as median (interquartile range) and categorical variables and number (%). This included treatment-related adverse events assessed by the investigator as at least possibly related to treatment. FACTG scores were analyzed using a mixed-effects covariance pattern model to utilize all the data collected over time with consideration of the variance-covariance matrix of the repeated measures. This method allows a general unstructured variance-covariance matrix and allows patients to have incomplete data across scheduled time points. All analyses were conducted using SAS 9.4 and SPSS 26.0.