BrUOG L317

IND Exempt 126924

Nivolumab and Ablation For Patients With Advanced Non-Small Cell Lung Cancer Progressing After at Least One Prior Therapy For Metastatic Disease: A Brown University Oncology Research Group Phase II

17.0 STATISTICS

The primary goal will be to determine the response rate of the combination of nivolumab and ablation.

17.1 Statistical Methods:

Let 'p' be the probability of response to treatment

Null hypothesis H0:p=p0

Alternate hypothesis H1:p>=p1

This study is a phase II non-randomized clinical trial. The primary endpoint of this trial is to determine the response rate for patients with metastatic non-small cell lung cancer treated with a combination of nivolumab and ablation, in the second line setting. Historically, the response rate of nivolumab alone in this setting has been about 20%.

Simon's minimax two-stage design (Simon, 1989) will be used. The null hypothesis that the true response rate is 20% will be tested against a one-sided alternative. In the first stage, 18 patients will be accrued. If there are 4 or fewer responses in these 18 patients, the study will be stopped early for futility. If at least 5 responses are obtained, additional patients will be accrued for a total of 33. The null hypothesis will be rejected if 11 or more responses are observed in 33 patients. This design yields a type I error rate of 0.05 and power of 80% when the true response rate is 40%.