
M E M O R A N D U M

TO: Dr. Blanke, Dr. LeBlanc and Data and Safety Monitoring Committee

FROM: Cathy Tangen, DrPH

DATE: April 24, 2018

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, April 13, 2018

1. CC S1316: *Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction.* S1316 study leadership updated the DSMC on their plans to temporarily close the trial and reopen with the randomization portion and surgical choice arms still in place (closing the no-surgical management choice arm). The DSMC is supportive and recognizes that this design change will take a few months to get through DCP and site-level regulatory review, and so we do not expect significant accrual between now and the fall DSMC meeting. However, we will continue to keep an eye on this trial.

2. LUNG S1403: *A Randomized Phase II/III Trial of Afatinib Plus Cetuximab versus Afatinib Alone in Treatment-Naïve Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer.* The DSMC recommends that accrual should be stopped and trial results should be released to the study team for reporting as a futility analysis threshold has been crossed.

3. LUNG S1400I: *A Phase III Randomized Study of Nivolumab Plus Ipilimumab Versus Nivolumab for Previously Treated Patients with Stage IV Squamous Cell Lung Cancer and No Matching Biomarker (LUNG-MAO Sub-Study).* The DSMC recommends that accrual should be stopped and trial results released to the study team for reporting as a futility analysis threshold has been crossed.

4. BREAST S1416: *Phase II Randomized Placebo-Controlled Trial of Cisplatin With or Without ABT-888 (Veliparib) in Metastatic, Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer, With or Without Brain Metastases.* The DSMC appreciated the study update from Dr. Barlow, the study biostatistician. The DSMC is concerned about the poor accrual of the brain metastases cohort. We recognize that the study team is in discussion with CTEP about the accrual goal for the entire trial, and we are supportive of that effort.

"Premature disclosure of confidential Data and Safety Monitoring Committee interim therapeutic results on SWOG by members of the Data Monitoring Committee will result in censure of that member by the Board of Governors. Censure options will include immediate loss of authorship in the study presentation and publication, decertification of status as a current and future Study Chair, and/or removal from leadership in the disease committee of record."

5. BREAST S1418: *A Randomized Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with ≥ 1 cm Residual Invasive Cancer or Positive Lymph Nodes (ypN+) after Neoadjuvant Chemotherapy.* The DSMC gives permission for the study statistician to provide a small subset of data (n=50) that has been appropriately disguised to Merck in order to prepare their data systems for regulatory filing should the trial be positive. Any future data transfers to Merck prior to the release of outcome data to the study team must be cleared by the DSMC.

6. GU S1216: *A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + TAK-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer.* The DSMC gives permission for data from the TM studies involving testosterone, circulating tumor cells and bone markers to be reported both at baseline and longitudinally in the pooled treatment arms, but no correlation with PSA response is allowed at the current time.

The following trials were reviewed by mail, not discussed at the meeting, and should proceed with no change:

Breast: S1007, S1207

Cancer Control: S0820, S1415CD, S1501

Gastrointestinal: S1505, S1613

Genitourinary: S0931, S1011, S1314, S1500, S1602, S1605

Leukemia: S1318, S1612

Lung: S1206, S1400, S1400F, S1400G, S1400K

Lymphoma: S1608

Melanoma: S1320, S1404, S1616

Myeloma: S1211

The next DSMC meeting is expected to be held tentatively on Friday, October 5, 2018 at 7:30 am CT, coinciding with the SWOG Group Meeting in Chicago. Details will be confirmed later.