
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 27, 2020

RE: SWOG DSMC – Draft minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, April 24, 2020

1. LUNG S1800A: *A Phase II Randomized Study of Ramucirumab plus MK3475 (Pembrolizumab) versus Standard of Care for Patients Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer (Lung-MAP Non-Matched Sub-Study).*

The Committee reviewed the first interim analysis and recommends the trial continue accrual as planned.

2. BREAST S1007: *A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer*

The Committee would like to see the same supplemental analysis that was presented at our spring 2020 meeting in the next interim analysis, complete with hazard ratios and p-values.

3. BREAST S1207: *Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer.*

The DSMC reviewed the interim analysis and recommends the trial continue as planned.

4. PROSTATE 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 reviewed the interim analysis and recommends the trial continue as planned.

5. CANCER CARE S1415CD: *Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating*

"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."

Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia – Trial Assessing CSF Prescribing Effectiveness and Risk (TrACER)

The DSMC reviewed the interim analysis recommends the trial continue as planned.

6. GENITOURINARY S1500: *A Randomized Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors in Metastatic Papillary Renal Carcinoma*

The request for early study results to be shared with subset of named GU leaders for study planning purposes has been approved. The DSMC expects each of the investigators sign a confidentiality agreement prior to seeing those results.

7. GENITOURINARY S1602: *A Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naïve High-Grade Non-Muscle Invasive Bladder Cancer.*

The DSMC reviewed the interim analysis and recommends the trial continue as planned.

8. MELANOMA S1616: *A Phase II Randomized Study of Nivolumab with Ipilimumab versus Ipilimumab Alone in Advanced Melanoma Patients Refractory to an Anti-PD-L1 or Anti-PD1 Agent.*

The DSMC reviewed the interim analysis and recommends the trial continue as planned.

9. CANCER CARE DELIVERY S1703: *Randomized non-inferiority trial comparing overall survival of patients monitored with serum tumor marker directed disease monitoring (STMDDM) versus usual care in patients with metastatic hormone receptor positive HER-2 negative breast cancer.*

The DSMC appreciated hearing from the study chair about the significant amendment that was recently approved for this trial to loosen eligibility and other aspects of the study to make it easier for sites to participate. The Committee will continue to monitor this study, and it expects to see an improvement in accrual by the fall 2020 meeting. We do recognize that it may be difficult to enroll patients in this trial during the COVID-19 pandemic

10. GASTROINTESTINAL S1815: *Nab-Paclitaxel versus Gemcitabine and Cisplatin in Newly Diagnosed Advanced Biliary Tract Cancers.*

Based on the accrual track record of this study, the DSMC is supportive of the pending amendment to increase the sample size of this trial to be able to detect a smaller treatment effect.

11. LUNG S1701: *A randomized phase II trial of carboplatin-paclitaxel with or without ramucirumab in patients with unresectable locally advanced, recurrent or metastatic thymic carcinoma.*

The DSMC noted the recent amendment that broadened the definition of thymic carcinoma, and the proactive accrual activities by the study team. Accrual has increased in the last few months.

We will continue to monitor the accrual for this study for improvements as the amendment gets cleared by IRBs.

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

NCTN Studies:

Breast: S1418, S1706

Gastrointestinal: S1613, S1922

Genitourinary: S0931, S1011, S1802, S1806

Leukemia: S1318, S1612, S1712

Lung: LUNGMAP, S1400F, S1900A, S1900B, S1900C, S1827

Lymphoma: S1608, S1826

Melanoma: S1404, S1801

Myeloma: S1803

NCORP Studies:

Prevention/Epidemiology: S0820

Symptom Control/Quality of Life: S1600, S1614

Survivorship: S1501

Palliative Care/End of Life: S1316, S1820

The next DSMC meeting is expected to be held tentatively on September 25, 2020, coinciding with the SWOG Group Meeting in Chicago. Details will be confirmed later.