SWOG CANCER RESEARCH NETWORK

May 15, 2020

TO: ALL NATIONAL CANCER CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NATIONAL COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP) COMPONENTS AND SUBCOMPONENTS

FROM: Charles D. Blanke, M.D. - Chair

RE: GUIDANCE ON REPORTING ADVERSE EVENTS TO INSTITUTIONAL REVIEW BOARDS FOR NIH-SUPPORTED MULTICENTER CLINICAL TRIALS (https://grants.nih.gov/grants/guide/notice-files/not99-107.html)

MEMORANDUM

All SWOG Phase III studies are monitored by our Data and Safety Monitoring Committee (DSMC). The Group policy regarding the function and composition of the DSMC is Policy #21, which may be found on the public portion of the Group web site at https://www.swog.org/sites/default/files/docs/2017-10/Policy21.pdf.

Copies of this document must be made available to local Institutional Review Boards (IRBs).

As outlined in the "GUIDANCE ON REPORTING ADVERSE EVENTS TO INSTITUTIONAL REVIEW BOARDS FOR NIH-SUPPORTED MULTICENTER CLINICAL TRIALS" (https://grants.nih.gov/grants/guide/notice-files/not99-107.html), the NIH requires that summary reports of adverse events be communicated from the DSMC to the IRBs at participating institutions.

The interim reports for SWOG studies are posted in the Report of Studies area on the members side of the Group web site at www.swog.org/. This site also contains the deliberations of the DSMC from their most recent meetings. A copy of the deliberations from the April 22, 2020 meeting is attached. The information from this report must be made available to your IRB.

If the DSMC has decided to make recommendations resulting in substantial changes to a study, those changes will be circulated in the form of a protocol amendment or a special notification (e.g., "Dear Physician" letter).

This memorandum serves to notify the NCI and SWOG Statistics and Data Management Center.

CTPM/sjh
Enclosure

cc: Cathy M. Tangen, Dr.P.H.
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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 appreciated the update from the first interim analysis that was conducted in November 2019.

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 Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile*

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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 a subset of named GU leaders for study planning purposes has been approved. The DSMC expects each of the investigators to 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. However, 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.

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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.