SWOG CANCER RESEARCH NETWORK

December 1, 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/about/policies-procedures.

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 November 9, 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: November 9, 2020

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, October 16, 2020

1. MELANOMA S1404: ***A phase III randomized trial comparing physician/patient choice of either high dose interferon or ipilimumab to MK- 3475 (pembrolizumab) in patients with high risk resected melanoma***

The DSMC agrees that if the required numbers of events for the final analysis of the co-primary endpoints have not occurred by March 2021, the final analysis should be conducted at that time (3.5 years post-accrual completion) as specified in the statistical analysis plan of the protocol.

2. GENITOURINARY S1806*: A Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer*

The DSMC reviewed the prespecified safety analysis of the first cohort of evaluable patients randomized to each arm. The higher grades of toxicity that were seen on the experimental arm are within the expected range, and there is no evidence of excessive immunologic toxicities with the addition of atezolizumab. No safety thresholds were crossed.

3. GENITOURINARY S0931: ***EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy: A Phase III Study.***

The proposed amended last interim and final analysis plan was approved by the DSMC, and we recognize that this amendment will now be submitted to CTEP for final review.

4. 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 (ypN1mi, ypN1-3) after Neoadjuvant Chemotherapy***

The study statistician summarized plans for using a new cut-point for the PDL-1 marker and its impact on the trial design. We appreciated the update and did not have any concerns with the process.

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5. MELANOMA S1801: ***A Phase II Randomized Study of Adjuvant versus Neoadjuvant MK-3475 (Pembrolizumab) for Clinically Detectable Stage III-IV High Risk Melanoma***

The prespecified safety interim analysis was reviewed, and because no thresholds for the neoadjuvant arm surgical safety and feasibility were reached and there were no other concerns, we recommend the trial continue as planned.

6. GENITOURINARY S1802: ***Phase III Randomized Trial of Standard Systemic Therapy (SST) versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer***

The DSMC recognizes and appreciates all the recruitment and promotional activities that have been undertaken to increase enrollment to this trial. We anticipate that accrual to a study with surgical randomization during Covid-19 has been challenging. However, an increase in the accrual rate is still needed to stay on pace with the study design assumptions. The DSMC will continue to monitor this study and will review accrual again in six months. We encourage the study team to reach out to prostate cancer patient advocacy groups as much as possible.

7. Cancer Care Delivery Research 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 Neutropenia – Trial Assessing CSF Prescribing Effectiveness and Risk (TrACER)***

The study team is given permission to conduct and publish an analysis using the G-CSF usage and febrile neutropenia endpoint data from the cohort that was enrolled in parallel to the clinical trial. No post-randomization trial data may be used until the final analysis is conducted.

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

NCTN Studies:

Breast: S1207, S1706
Breast S1007 is currently under review, and the DSMC minutes will be amended when resolved. There are no safety concerns.
Gastrointestinal: S1613, S1815, S1922
Genitourinary: S1011, S1216, S1602
Leukemia: S1318, S1712
Lung: LUNGMAP, S1701, S1827, S1914, S1929, S1800A, S1900A, S1900B, S1900C
Lymphoma: S1608, S1826, S1918
Melanoma: S1616
Myeloma: S1803

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NCORP Studies:
Prevention/Epidemiology: S0820
Symptom Control/Quality of Life: S1600, S1614
Survivorship: S1501
Cancer Care Delivery Research: S1703
Palliative Care/End of Life: S1316, S1820

The next DSMC meeting is expected to be held tentatively on Friday, April 23, 2021, coinciding with the SWOG Spring Group Meeting. Details will be confirmed later.