SWOG CANCER RESEARCH NETWORK

May 1, 2021

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 April 23, 2021 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.
Nathan Eriksen
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Dana B. Sparks, M.A.T.

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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 23, 2021

RE: SWOG DSMC – Draft minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, April 23, 2021

1. GENITOURINARY S0931 EVEREST: ***EVErolimus for Renal Cancer Ensuing Surgical Therapy: A Phase III Study*** The DSMC reviewed the results of the final interim analysis and recommends the study continue as planned.

2. 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 results of the third interim analysis and recommends the study continue as planned.

3. 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 DSMC reviewed the data request for 1, 2 and 3-year survival estimates from the pooled treatment arms for the purpose of future trial design. The request was declined at the current time. The DSMC would consider revisiting this request when all patients have been enrolled and received protocol treatment for at least several months.

4. LUNG S1800A *(Lung-MAP Sub-Study):* ***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 DSMC reviewed the second interim analysis and recommends the trial continue as planned.

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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 DSMC reviewed the safety monitoring that was prespecified to occur after 60 eligible patients had been randomized to the neoadjuvant arm. As no threshold was crossed, the Committee recommends the trial continue as planned.

6. GENITOURINARY S1806: ***A Phase III Randomized Trial of Concurrent Chemoradiotherapy with or without Atezolizumab in Localized Muscle Invasive Bladder Cancer*** The DSMC reviewed the data analysis request, and it is denied at the current time. When there is more adverse event information, the DSMC would be willing to revisit this request.

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 discussed, in a preliminary fashion, a potential data request for this study. A more formal request is expected to be forthcoming in the fall of 2021.

8. SYMPTOM CONTROL AND QOL S1600: ***A Randomized Phase III Double-Blind Clinical Trial Evaluating the Effect of Immune-Enhancing Nutrition on Radical Cystectomy Outcomes*** The DSMC reviewed the formal assessment of accrual and congratulates the study team for their successful accrual to this study.

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 recognizes the challenges of conducting this trial during the COVID-19 pandemic. The Committee has reviewed the changes to the eligibility criteria for this study and all the outreach activities to increase accrual. Although there is concern about the accrual rate, we encourage the study team to continue to work on improving enrollment. It is recommended that the study team reach out to patient advocates to enhance trial visibility. We will continue monitoring accrual to this study.

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

NCTN Studies:
Breast: S1706
Gastrointestinal: S1613, S1815, S1922, S2001
Genitourinary: S1011, S1802, S1931, S1937
Leukemia: S1318, S1712, S1925
Lung: LUNGMAP, S1701, S1827, S1914, S1929, S1900A, S1900B, S1900C

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Lymphoma: S1608, S1826, S1918
Melanoma: S1616, S2000
Myeloma: S1803

NCORP Studies:
Prevention/Epidemiology: S0820, S1904
Symptom Control/Quality of Life: S1614
Survivorship: S1501
Palliative Care/End of Life: S1820

The next DSMC meeting is expected to be held tentatively on Friday, October 15, 2021, coinciding with the SWOG Group Meeting in Chicago. Details will be confirmed later.