Southwest
Oncology Group
A National Clinical Research Group

May 15, 2010

TO: ALL SOUTHWEST ONCOLOGY GROUP MEMBER, CCOP, UCOP AND AFFILIATE MEDICAL ONCOLOGISTS, SURGEONS, RADIATION ONCOLOGISTS, PATHOLOGISTS AND CLINICAL RESEARCH ASSOCIATES; ACRIN, ECOG, CALGB, NCIC-CTG, NCCTG, RTOG, COG, ACOSOG, NSABP, EORTC, IBCSG, BMT-CTN, AND CTSU

FROM: Laurence H. Baker, D.O. - Chairman

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

MEMORANDUM

All Southwest Oncology Group 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 http://swog.org/Visitors/download/policies/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 (http://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 Southwest Oncology Group studies are posted in the Report of Studies area on the members side of the Group web site at https://swog.org/. This site also contains the deliberations of the DSMC from their most recent meetings. A copy of the deliberations from the April 7, 2010 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).

PC/dbs

Enclosure

cc: Cathy M. Tangen, Dr.P.H.
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M E M O R A N D U M

TO: Dr. Baker, Dr. Crowley and the Data and Safety Monitoring Committee

FROM: Cathy Tangen, DrPH

DATE: April 7, 2010

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting via Conference Call of Wednesday, April 7, 2010

1. Study Design Assumptions
   Gastrointestinal S0518 – Phase III Randomized Comparison of Depot Octreotide Plus Interferon Alpha Versus Depot Octreotide Plus Bevacizumab in Advanced, Poor Prognosis Carcinoid Patients. The Committee appreciated the opportunity to review study design assumptions, and it expects the S0518 study leadership will have further discussions with CTEP about potential adjustments to the design.

2. Poor Accrual
   Genitourinary S0337– A Phase III Blinded Study of Immediate Post-TURBT Instillation of Gemcitabine Versus Saline in Patients with Newly Diagnosed or Occasionally Recurring Grade I/II Superficial Bladder Cancer. The Committee recognizes that accrual has increased somewhat over the last six months, and a number of steps are being taken to increase the number of investigators involved in this study. The DSMC will review the accrual rate in six more months.

3. Planned Interim Analysis and Final Reporting
   Leukemia S0325 - A Phase IIb Study of Molecular Responses to Imatinib, at Standard or Increased Doses, or Dasatinib for Previously Untreated Patients with Chronic Myelogenous Leukemia in Chronic Phase. The DSMC recognizes that, because of logistical issues, the interim analysis will not be conducted now, but a final analysis will be conducted in several months. The Chair of the DSMC would like to receive a copy of that analysis before it is publicly reported.

4. Poor Accrual
   Leukemia S0521 - A Randomized Trial of Maintenance versus Observation for Patients with Previously Untreated Low and Intermediate Risk Acute Promyelocytic Leukemia, Phase III. This study has had slow accrual since its activation on June 1, 2007. Recently, Step 1 accrual has been modest, reaching about 50% of the expected rate, but the fraction

of those patients going on to post-consolidation randomization is lower than expected. As of March 17, 2010, 41 patients have been randomized to post-consolidation. Over the past 6 months, the randomization rate is estimated to be 36 patients per year. If the randomization goal is 350 patients, that will mean 8 additional years of accrual and three years of follow-up The total study duration will be about 14 years. Additionally, the DSMC doesn't see hope for accrual to increase since the two primary drugs are commercially available for APL. The DSMC recommends that this study be closed due to poor accrual.

5. Data Request
   Genitourinary S9346 - Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer. ECOG study leadership from E3804 has permission to receive median survival estimates for the subset of patients with high risk disease who received continuous androgen deprivation treatment. This information will be used to assess the study design assumption of median survival for their trial.

6. Data Request
   Melanoma S0008 – A Phase III Trial of High Dose Interferon Alpha-2b versus Cisplatin, Vinblastine, DTIC plus IL2 and Interferon in Patients with High Risk Melanoma. The members of the study leadership, specified in the request to the DSMC, have permission to view survival and relapse-free survival curves labeled by treatment arm with corresponding p-values as needed for planning purposes. The actual outcome information is confidential until publicly reported.

7. Interim Analysis
   Breast S0500 – A Randomized Phase III Trial to Test the Strategy of Changing Therapy Versus Maintaining Therapy for Metastatic Breast Cancer Patients Who Have Elevated CTC Levels at First Follow-up Assessment. The first interim analysis was reviewed. No boundaries have been crossed, so the DSMC recommends that this study continue as planned.

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

Breast
S0221
S0226
S0307

Cancer Control
S0230
S0701
S0715

Gastrointestinal
S0502
S0600
S0727

Genitourinary
S0421

Lung
S0802
S0819

Lymphoma
S0016

Myeloma
S0777

The next DSMC meeting will be held at the SWOG Group Meeting in Chicago scheduled ***tentatively*** for Friday, October 22, 2010 from 5-8 pm CT. Confirmation of date and time will follow.