Southwest
Oncology Group
A National Clinical Research Group

May 15, 2009

TO: ALL SOUTHWEST ONCOLOGY GROUP MEMBER, CCOP, UCOP AND AFFILIATE MEDICAL ONCOLOGISTS, SURGEONS, RADIATION ONCOLOGISTS, PATHOLOGISTS AND CLINICAL RESEARCH ASSOCIATES; 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, 2009 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: Members of the SWOG Data and Safety Monitoring Committee

FROM: Cathy Tangen, DrPH

DATE: April 7, 2009

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting via Conference Call of Tuesday, April 7, 2009

1. Interim Analysis and Data Request
   Genitourinary S9346 – Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer. The third formal interim analysis was reviewed, and the Committee recommends that the study continue as planned. A data request to report survival for those patients who were assigned continuous AD was approved.

2. Interim Analysis
   Genitourinary S0421 – Docetaxel and Atrasentan versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer. The first formal interim analysis was reviewed, and the Committee recommends the trial continue as planned.

3. 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. There have been complications that have kept CALGB from participating, but they are expected to put patients on the trial shortly. Disease committee chairs across the three cooperative groups are supportive of this trial. We anticipate accrual will increase, and we will review the study again at our fall 2009 meeting.

4. Poor Accrual
   Genitourinary S0337 – Immediate Post-TURBT Instillation of Gemcitabine Versus Saline in Patients with Newly Diagnosed or Occasionally Recurring Grade I/II Superficial Bladder Cancer. Accrual has been slow for this trial, which opened on July 15, 2007. An amendment relaxing eligibility went in to effect February 1, 2009. The CTEP accrual rule will be applied at the end of the summer for quarters 7 and 8. The DSMC will review this trial again in fall 2009.

5. Toxic Deaths and Timing of Interim Analyses
   Leukemia S0106 – A Phase III Study of the Addition of Gemtuzumab Ozogamicin Arabinoside Followed by Consolidation and Subsequent Randomization to Post-Consolidation Therapy with Gemtuzumab Ozogamicin or No Additional Therapy for Patients Under Age 61 with Previously Untreated De Novo Acute Myeloid Leukemia. The Committee carefully reviewed the presumed treatment related deaths from each arm of the induction portion of the trial. Although the Committee recommends the study continue, the DSMC membership wish to see the formal interim analysis of the induction efficacy data within the next 60 days. Additional possible toxic induction deaths should continue to be reported to the DSMC chair prior to the next meeting.

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 study leadership has requested permission to perform analysis of the pooled treatment arms to identify risk groups based on relapse-free survival, distant metastasis-free survival and overall survival. Clinicopathologic and molecular markers will be correlated to these outcomes. The Committee gave permission for these analyses to go forward.

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

Breast
S0221
S0226
S0307
S0500

Cancer Control
S0230

Gastrointestinal
S0502
S0518
S0600
S0727

Genitourinary
S9917
S0717

Leukemia
S0325

Lymphoma

S9704
S0016
S0410

Myeloma
S0777

The next DSMC meeting will be held at the SWOG Group Meeting in Chicago scheduled ***tentatively*** for Friday, October 23, 2009 from 5-8 pm CT. Confirmation of date and time will follow.