Southwest
Oncology Group
A National Clinical Research Group

November 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 October 23, 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

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M E M O R A N D U M

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

FROM: Cathy Tangen, DrPH

DATE: October 30, 2009

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, October 23, 2009

1. Interim Analysis
   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 last formal interim analysis was assessed, and the Committee recommends the study continue as planned.

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

   Breast S0226 – Phase III Randomized Trial of Anastrozole Versus Anastrozole and Fulvestrant as First Line Therapy for Post Menopausal Women with Metastatic Breast Cancer. The first formal interim analysis was reviewed, and the Committee recommends the trial continue as planned. A similarly designed study from the U.K. will report results of its trial at the San Antonio Breast Cancer Symposium in December, 2009. Once available, the DSMC Committee will work with the S0226 study leadership to assess the safety and efficacy results from that trial, and communicate to the patients of the current SWOG trial as needed.

2. 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. Although the DSMC recognizes this is an important trial, they have serious concerns about the much lower than expected accrual rate. At the current accrual rate, it is very doubtful that the trial will ever meet its objectives. If the study is not averaging 75 patients per year at the time of the spring meeting, consideration will be given to recommending closure of the study.

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 very slow for this trial, which opened on July 15, 2007. An amendment relaxing eligibility has been approved by CTEP and will be mailed out on November 15, 2009. The DSMC will expect to see 50% of the projected accrual rate (7/month) by the spring meeting, or consideration will be given to recommending closure of this study.

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

Breast
S0221
S0307
S0500

Cancer Control
S0230
S0701

Gastrointestinal
S0502
S0518
S0600
S0727

Genitourinary
S9346
S9917

Leukemia
S0325

Lung
S0802
S0819

Lymphoma
S9704
S0016
S0410

Myeloma
S0777

The next DSMC meeting will be scheduled as a conference call 1-2 weeks prior to the SWOG Group Meeting in San Francisco (April 14-17, 2010). Confirmation of date and time will follow.