SWOG
Leading cancer research. Together.

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November 15, 2011

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 October 14, 2011 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 Southwest Oncology Group Statistical Center.

PC/dbs

Enclosure

cc: Cathy M. Tangen, Dr.P.H.
Nathan Erickson
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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 19, 2011

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, October 14, 2011

Interim Analysis

1. Breast S0221 – Phase III Trial of Continuous Schedule AC + G Vs. Q 2 Week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 Weeks as Post-Operative Adjuvant Therapy in Node-Positive or High-Risk Node-Negative Breast Cancer. The DSMC reviewed the planned interim analysis. As no statistical boundaries were crossed, the recommendation is that the study should continue as planned.

2. Breast S0500 – A Randomized Phase III Trial to Test the Strategy of Changing Therapy Versus Maintaining Therapy for Metastatic Breast Cancer Who Have Elevated Circulating Tumor Cell Levels at First Follow-up Assessment. The DSMC reviewed the planned interim analysis. As no statistical boundaries were crossed, the recommendation is that the study should continue as planned.

3. Breast S0307 – A Phase III Trial of Bisphosphonates as Adjuvant Therapy for Primary Breast Cancer. The DSMC reviewed the planned interim analysis. Since no statistical boundaries were crossed, the recommendation is that the study should continue as planned. The study leadership's data request was declined based on a weighing of the pros and cons of releasing information while the trial is ongoing.

Safety Monitoring

4. Lung S0819 – A Randomized Phase III Study Comparing Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer. The DSMC carefully reviewed the adverse events for the four combinations of treatment arm and bevacizumab eligible patients. The recommendation is that the study should continue as planned, but the DSMC would like to see another detailed reporting of adverse events in three months time. The details of the requested report will be communicated to the study leadership.

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

Breast
S0226
S0800
S1007

Gastrointestinal
S0518

Genitourinary
S0337
S0925
S0931
S1011

Gynecologic
S0904

Lung
S0802

Myeloma
S0777

The next DSMC meeting will be held by conference call just prior to the spring 2012 group meeting (April 12-14, 2012).

"Premature disclosure of confidential Data and Safety Monitoring Committee interim therapeutic results on SWOG by members of the Data Monitoring Committee will result in censure of that member by the Board of Governors. Censure options will include immediate loss of authorship in the study presentation and publication, decertification of status as a current and future Study Coordinator, and/or removal from leadership in the disease committee of record."