SWOG
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May 1, 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 April 1, 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: April 1, 2011

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, April 1, 2011

Interim Analysis

1. Genitourinary S0421 – Docetaxel and atrasentan versus docetaxel and placebo for patients with advanced hormone refractory prostate cancer. The DSMC reviewed the planned final interim analysis. Based on the observed null result and the extremely unlikely chance that this conclusion will change with more events, the DSMC recommends this study be reported now instead of the planned final analysis 18 months from now.

2. Gastrointestinal S0518 – A phase III prospective randomized comparison of depot octreotide plus interferon alpha versus depot octreotide plus bevacizumab in advanced, poor prognosis carcinoid patients. The results of the first interim analysis were reviewed, and the DSMC recommends the study continue as planned.

3. Cancer Control S0230 – A phase III trial of LHRH analog administration during chemotherapy to reduce ovarian failure following chemotherapy in early stage, hormone-receptor negative breast cancer. The results of the first interim analysis were reviewed, and no boundaries have been crossed. The recommendation is that the study should continue, but the DSMC looks forward to a re-evaluation of the study design in fall, 2011 by the study leadership. Reducing the proposed length of the trial would be encouraged.

4. Lung S0802 – A randomized phase II trial of weekly topotecan with and wihtou AVE0005 in patients with platinum-treated extensive stage small cell lung cancer. The results of the one interim analysis were reviewed, and the DSMC recommends the trial continue as planned.

Timing of Final Analysis

5. Breast S0226 – A phase III randomized trial of anastrozole versus anastrozole and fulvestrant as first line therapy for post menopausal women with metastatic breast cancer. The DSMC gives study leadership permission to prepare an abstract for the San Antonio Breast Cancer Symposium to be held December, 2011. We expect the data to be updated in October as specified in their request.

6. 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 DSMC gives permission for the study leadership to prepare an ASCO 2012 abstract which may include survival results.

External Information

7. Breast S0800 – A randomized phase II trial of weekly nanoparticle albumin bound paclitaxel with or without bevacizumab, either preceeded by or followed by Q 2 week AC as neoadjuvant therapy for inflammatory and locally advanced her-2/neu negative breast cancer. The DSMC reviewed the Memorandum – Dear Investigator Letter that was written by CTEP, and they approve of its content. The DSMC encourages the continued careful monitoring of adverse events from this trial.

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

Breast
S0221
S0307
S0500
S1007

Cancer Control
S0230
S0701
S0715

Gastrointestinal
S0727

Genitourinary
S9346
S0337
S0925

Gynecologic
S0904

Lung
S0819

Myeloma
S0777

The next DSMC meeting will be held at the downtown Chicago Hyatt on Friday, October 14, 2011.