
M E M O R A N D U M

TO: Dr. Blanke, Dr. LeBlanc and Data and Safety Monitoring Committee
FROM: Cathy Tangen, DrPH
DATE: May 3, 2017
RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, April 28, 2017

1. Genitourinary S1011 – *A Phase III Surgical Trial to Evaluate the Benefit of a Standard Versus an Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Muscle Invasive Urothelial Cancer.* The second formal interim analysis was conducted as planned. No statistical boundaries were crossed. The DSMC recommends the study continue as planned.

2. Myeloma S1211: *A Randomized Phase I/II Study of Optimal Induction Therapy of Bortezomib, Dexamethasone, and Lenalidomide with or without Elotuzumab for Newly Diagnosed high Risk Multiple Myeloma.* The one formal interim analysis for this trial was conducted as planned. No statistical boundaries were crossed. The DSMC recommends the study continue as planned.

3. CC S1316: *Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction.* The DSMC continues to be concerned about the lack of patient randomizations on this study. The DSMC will review this trial again in six months and will expect substantial improvement in the randomization rate once Canadian and Latin American sites have started enrolling. The study team should be communicating with the Division of Cancer Prevention at NCI about the accrual challenges for the randomization portion of the study and planned strategies for improving the accrual.

4. LUNG S1403: *A Randomized Phase II/III Trial of Afatinib Plus Cetuximab versus Afatinib Alone in Treatment-Naïve Patients with Advanced, EGFR Mutation Positive Non-Small Cell Lung Cancer.* The DSMC expressed concern about this trial's low accrual rate. The study team reported that they are in discussion with CTEP about redesigning the trial to require a smaller sample size. The DSMC encourages the study team to quickly submit a study design amendment to the NCI for review.

5. Gastrointestinal S1505: *A Randomized Phase II Study of Perioperative mFOLFIRINOX versus Gemcitabine/nab-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma.* The DSMC understands that the current definition of "failure to reach resection" as specified in the

"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 Chair, and/or removal from leadership in the disease committee of record."

statistical section of the protocol does not adequately reflect the intention of the trial. The DSMC strongly encourages the study leadership to carefully consider precise language to specify what “getting to resection” means, and what the threshold should be and whether that should vary by treatment. The study team is encouraged to quickly work out the details of the study amendment with CTEP so that the temporary closure may be resolved.

6. Lung S1400 and its substudies: *A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP).* The current status of the screening step and substudies was discussed. There were no recommendations or concerns.

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

Breast: S1007m S1207, S1416, S1418

Cancer Control: S0820, S1200, S1415CD

Gastrointestinal: S1513

Genitourinary: S0931, S1216, S1314, S1500, S1602, S1605

Leukemia: S1318

Lung: S1206, S1300

Melanoma: S1320, S1404

Myeloma: S1304

The next DSMC meeting is expected to be held in-person tentatively on Friday, October 13, 2017 at 7:30 am CT, coinciding with the SWOG Group Meeting in Chicago. Details will be confirmed later.