



SWOG

A National
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Research
Group

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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 4, 2015
RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, May 1, 2015

1. Prevention S0820 – Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES). The DSMC appreciated the helpful and thorough presentation from the study leadership. The DSMC remains concerned about the current accrual rate for this trial and the feasibility of addressing the primary objective. Based on amendments expanding the patient population and the upcoming closure of competing studies, there is an expectation of a modest increase in the study's accrual rate by the October 2015 DSMC meeting. However, the DSMC expects a substantial increase in the accrual rate after January 2016. For that reason, the DSMC will review again in the fall to ensure the accrual rate is going in the correct direction and then review very critically at the April 2016 meeting.
2. Leuk S1203 – A Randomized Phase III Study of Standard Cytarabine Plus Daunorubicin (7+3) Therapy or Idarubicin with High Dose Cytarabine (IA) Versus IA with Vorinostat (IA+V) in Younger Patients with Previously Untreated Acute Myeloid Leukemia. After reviewing the second and third planned interim analysis, the DSMC recommends the following: In terms of the response assessment among the first 100 patients on each induction arm (second interim analysis), the recommendation is that the IA+V be closed to further enrollment due to futility defined as a CR rate on that arm that is less than the CR rate on the 7+3 or IA arm. In terms of the third interim analysis which compares event-free survival between the IA and 7+3 arms, the recommendation is that the two arms should continue as planned.
3. GU 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 DSMC reviewed the first planned interim analysis for this trial, and recommends the trial should continue as planned.
4. GU S0931 - EVEREST: EVERolimus for Renal Cancer Ensuing Surgical Therapy: A Phase III Study. The DSMC reviewed the first planned interim analysis for this trial, and recommends the study should continue as planned.

"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."

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

Breast

S1007, S1207, S1222

Cancer Control

S0812, S1105, S1200, S1202, S1204, S1316

Gastrointestinal

S1201, S1310, S1406

Genitourinary

S1216, S1314

Lung

S0819, S0905, S1300, S1400, S1400A – S1400E, S1403

Melanoma

S1320

Myeloma

S1211, S1304

The next DSMC meeting is tentatively expected to be held by conference call on Friday, October 9, 2015, coinciding with the SWOG Group Meeting in Chicago. Details will be confirmed later.