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## M E M O R A N D U M

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TO: Dr. Blanke, Dr. LeBlanc and Data and Safety Monitoring Committee  
FROM: Cathy Tangen, DrPH  
DATE: October 11, 2015  
RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, October 9, 2015

1. Prevention S0820 – Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES). The DSMC is encouraged that the Step 0 administrative registration is being used, and we understand that the competing trial from the Alliance will complete accrual and close very soon. The DSMC remains concerned that there has not been a modest increase in accrual despite rectal cancer patients becoming eligible. The DSMC expects that accrual will improve over the next six months. The Committee will review this trial 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 fourth planned interim analysis comparing event-free survival between the IA and 7+3 arms, the DSMC recommends the trial should continue as planned.

3. Lung S1300 - A Randomized Phase II Trial of Crizotinib Plus Premetrexed versus Premetrexed Monotherapy in Alk-Positive Non-Squamous NSCLC Patients Who Have Progressed Systematically after Previous Clinical Benefit from Crizotinib. The DSMC recognizes that the changing treatment landscape in this disease setting makes the originally designed trial infeasible to accrue to. We encourage the study team and CTEP to activate the new design amendment quickly so the study may answer the new primary objective. The DSMC will continue to monitor the accrual to this trial after the amendment.

4. Cancer Control S1105: Randomized Trial of Text-Messaging Intervention to Reduce Early Discontinuation of Adjuvant Aromatase Inhibitor Therapy in Women with Early Stage Breast Cancer. The DSMC gives approval for the study team to conduct a correlative analysis of baseline urinary AI levels with other trial demographics and baseline PRO measures while they wait for the endpoint data to mature on this trial.

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

Breast

S1007, S1207

Cancer Control

S1200, S1202, S1316

Gastrointestinal

S1201, S1313, S1406

Genitourinary

S0931, S1011, S1216, S1314

Lung

S0905, S1300, S1400, S1400A – S1400D, S1403

Melanoma

S1320

Myeloma

S1211, S1304

The next DSMC meeting is tentatively expected to be held by conference call on Friday, April 29, 2016, coinciding with the SWOG Group Meeting in San Francisco. Details will be confirmed later.