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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 18, 2017  
RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, October 13, 2017

**1. CC S1316:** *Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction.* With a projected completion of accrual to the observational cohort in approximately six months, the DSMC has asked the study leadership for some specific details about their accrual limit for the observational cohort. The DSMC recommends that after the cohort accrual goal is reached, the randomization portion of the trial may continue for a probationary six-month period. The DSMC would then carefully evaluate the feasibility of randomizing patients to this trial and evaluate the ability to achieve the objectives of the trial.

**2. LUNG S1206:** *A Dose Finding Study Followed by a Phase II Randomized, Placebo-Controlled Study of Valiparib (ABT-888) Added to Chemoradiotherapy with Carboplatin and Paclitaxel for Unresectable Stage III Non-Small Cell Lung Cancer.* The DSMC appreciated the update on this trial, and accepts the proposed plan to close the study in the near future.

**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 appreciated the update on the proposed study design changes for this trial.

**5. Melanoma S1320:** *A Randomized Phase II Trial of Intermittent versus continuous Dosing of Dabrafenib and Trametinib in BRAF Mutant Melanoma.* After reviewing the one planned interim analysis, the DSMC recommends the trial continue as planned.

**6. Melanoma S1404:** *A Phase III Randomized Trial Comparing Physician/Patient Choice of Either High Dose Interferon or Ipilimumab to MK-3475 (pembrolizumab) in Patients with High Risk Resected Melanoma.* The DSMC appreciated the update on external trial information that was reported at ESMO. We also had the opportunity to review the Dear Patient and Dear Investigator letters that had been previously reviewed and edited by the DSMC chair. The DSMC reviewed the detailed data request from the study statistician for the study sponsor, and we agree with the plan that she has described in detail.

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"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."

**7. GU S0931 - EVEREST: EVerolimus for Renal Cancer Ensuing Surgical Therapy: A Phase III Study.** The DSMC reviewed the second planned interim analysis for this trial, and recommends the study should continue as planned.

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

Breast: S1007, S1207, S1416, S1418

Cancer Control: S0820, S1415CD

Gastrointestinal: S1505, S1513

Genitourinary: S1011, S1216, S1314, S1500, S1602, S1605

Leukemia: S1318

Lung: S1400, S1400I, S1400G

Melanoma: S1616

Myeloma: S1211, S1304

The next DSMC meeting is expected to be held tentatively on Friday, April 13, 2018 at 7:30 am PT, coinciding with the SWOG Group Meeting in San Francisco. Details will be confirmed later.