Statistical Center
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North, M3-C102
Seattle, Washington 98109-1024
Phone: 206/667-4623
FAX 206/667-4408

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 2, 2016
RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, April 29, 2016

1. **Prevention S0820** – *Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES).* The DSMC is encouraged to see that the Step 0 administrative registrations are increasing, and we hope to see those translate into trial randomizations soon. We acknowledge that the Study Chair has done a commendable job trying to build momentum for this trial. The DSMC is concerned that the promise of increased accrual with the Alliance trial closure in the fall of 2015 has not happened. There are trial advocacy activities planned at the NCI in the summer. It is hoped that this will lead to greater participation, particularly among those who had enrolled patients in the prior Alliance trial. The DSMC will carefully review this trial again in the Fall of 2016 for feasibility.

2. **Leukemia 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 fifth planned interim analysis comparing event-free survival between the IA and 7+3 arms, the DSMC recommends the trial data be released to the study leadership for reporting. This recommendation of earlier reporting is based on a pre-specified analysis that crossed a statistical threshold.

3. **Genitourinary S0931** – *EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, a Phase III Study*. The DSMC gives permission for the study investigators to report the results of an analysis of pharmacokinetic measures correlated with adverse events in the Fall of 2016.

4. **Quality of Life S1013**: *A prospective study of Epidermal Growth Factor Receptor inhibitor-Induced Dermatologic Toxicity: Validation of the Functional Assessment of Cancer Therapy-EGFRI 18) Questionnaire for EGFRI-Induced Skin Toxicities*. The DSMC gives permission for means and standard deviations of the QOL instrument to be shared with Drs. Wagner and Cella for the purposes of study design considerations for their new trial. This information must be kept confidential and not publicly reported. The study leadership of S1013 are supportive of this data sharing request.

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5. **Breast S1207**: *Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer*. The DSMC encourages the study leadership to be very proactive in terms of providing guidance for symptom management in order to minimize the number of patients going off protocol treatment prematurely. The DSMC would like the study team, over the next 6-12 months, to continue to evaluate whether an increase in the sample size may be warranted.

6. **Genitourinary S1216**: *A Phase III Randomized Trial Comparing Androgen Deprivation Therapy + Tak-700 with Androgen Deprivation Therapy + Bicalutamide in Patients with Newly Diagnosed Metastatic Hormone Sensitive Prostate Cancer*. Since no statistical boundaries were crossed during the first formal interim analysis, the DSMC recommends the study continue as planned.

7. **Myeloma S1304**: *A Phase II Randomized Study Comparing Two Doses of Carfilzomib with Dexamethasone for Multiple Myeloma Patients with Relapsed or Refractory Disease*. No statistical boundaries were crossed for the interim analysis so the recommendation is that that the study should continue as planned.

8. **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.

9. **CC S1316**: *Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction.* The DSMC recognizes that additional sites have been added as participants. We will carefully review the accrual rate and randomization/patient choice distribution at our next meeting in September 2016.

10. **Gastrointestinal S1406**: *A Randomized Phase II Study of Irinotecan and Cetuximab With or Without Vermurafenib in BRAF Mutant Metastatic Colorectal Cancer*. The one futility interim analysis did not cross the statistical threshold so the recommendation is that the study should continue as planned.

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

Breast
S1007

Cancer Control
S1105, S1200, S1202

Gastrointestinal
S1313, S1505

Genitourinary
S1011, S1314

Lung
S0905, S1300, S1403

Melanoma
S1320. S1404

Myeloma
S1211

The next DSMC meeting is expected to be held in person, tentatively on Friday, September 16, 2016, coinciding with the SWOG Group Meeting in Chicago. Details will be confirmed later.