MEMORANDUM

TO: Dr. Blanke, Dr. LeBlanc and Data and Safety Monitoring Committee

FROM: Cathy Tangen, DrPH

DATE: October 9, 2019

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting on Friday, October 4, 2019

1. GENITOURINARY S0931: EVerolimus for Renal Cancer Ensuing Surgical Therapy: A Phase III Study.
The formal interim analysis was evaluated, and the DSMC recommends that the study continues as planned.

2. BREAST S1007: A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer with Recurrence Score (RS) of 25 or Less. RxPONDER: A Clinical Trial Rx for Positive Node, Endocrine Responsive Breast Cancer
The DSMC reviewed the planned interim analysis. The recommendation is that the study continues as planned. The study statistician has been asked to provide some additional analyses for the spring 2020 DSMC meeting.

3. PROSTATE 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
The DSMC approved a translational medicine statistical analysis proposal using PSA response and progression-free survival endpoints, conditional on the sampling design set forth by the study statistician so that treatment effects cannot be evaluated.

4. SURVIVAL S1501: Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III
The DSMC reviewed the accrual rate over time for this trial. The Committee appreciated the discussion with the study co-chairs, particularly related to the challenge of validating ECHO assessment centers. Accrual rate now seems to be on track, and the DSMC has no other requests from the study team.

"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."
5. **LUNG S1701**: A Randomized Phase II Trial of Carboplatin-Paclitaxel with or Without Ramucirumab in Patients with Unresectable Locally Advanced, Recurrent, or Metastatic Thymic Carcinoma

The DSMC recognized that this is a rare disease and the trial has been opened for only one year. The study can continue as planned. However, the study team should be prepared to update the DSMC in 6 months with a report of the number of centers that have the study opened and strategies for enhancing enrollment.

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

**NCTN Studies:**
- Breast: S1207, S1416, S1418, S1706
- Gastrointestinal: S1505, S1613, S1815
- Genitourinary: S1011, S1500, S1602, S1605, S1802, S1806
- Leukemia: S1318, S1612, S1712
- Lung: LUNGMAP, S1400F, S1800A, S1900A
- Lymphoma: S1608, S1826
- Melanoma: S1320, S1404, S1616, S1801
- Myeloma: S1211

**NCORP Studies:**
- Prevention/Epidemiology: S0820
- Symptom Control/Quality of Life: S1600, S1614
- Survivorship: S1316
- Cancer Care Delivery Research: S1415CD, S1703

The next DSMC meeting is expected to be held tentatively on Friday, April 24th, 2020, coinciding with the SWOG Group Meeting in San Francisco. Details will be confirmed later.