
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: October 9, 2018

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, October 5, 2018

1. BREAST S1416: *Phase II Randomized Placebo-Controlled Trial of Cisplatin With or Without ABT-888 in Metastatic Triple-Negative Breast Cancer and/or BRCA Mutation-Associated Breast Cancer, With or Without Brain Metastases.*

The DSMC reviewed an informal assessment of the outcome data now that more tissue has been evaluated since the spring 2018 meeting. They recommend the study continue 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 of 25 or Less.*

The DSMC evaluated the first planned interim analysis, and the recommendation is that the study continue as planned. At the next planned analysis in one year, the DSMC requests that analyses conducted by stratification factors be included in the report.

3. GENITOURINARY S1605: *Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer.* Based on the study update given by the study chair regarding trends in the ineligibility rate and the status of a comprehensive amendment that is currently at CTEP, the DSMC is comfortable with the progress of this study, and no additional action is needed at the present time.

4. MELANOMA S1320: *A Randomized Phase II Trial of Intermittent versus Continuous Dosing of Dabrafenib and Trametinib in BRAF Mutant Melanoma.* The DSMC agrees with the study team's plan to submit an amended study accrual interval and related study design changes to CTEP.

5. SURVIVORSHIP S1316: *Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction.* The DSMC continues to be concerned about accrual to this study, particularly now

that the non-surgical, non-randomized arm was recently closed. We recognize that there has not been much time between the amendment activation and the DSMC meeting. We will evaluate this trial accrual carefully at the spring 2019 meeting.

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

NCTN Studies:

Breast: S1207, S1418, S1706

Gastrointestinal: S1505, S1613

Genitourinary: S0931, S1011, S1216, S1314, S1500, S1602, S1605

Leukemia: S1318, S1612, S1712

Lung: S1400, S1400F, S1400K

Lymphoma: S1608

Melanoma: S1404, S1616

Myeloma: S1211

NCORP Studies:

Prevention/Epidemiology: S0820

Survivorship: S1501

Cancer Care Delivery Research: S1415CD, S1703

The next DSMC meeting is expected to be held tentatively on Friday, April 26, 2019 at 7:30 am PT, coinciding with the SWOG Group Meeting in San Francisco. Details will be confirmed later.