
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: April 29, 2019

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, April 26, 2019

1. 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 reviewed the first formal interim analysis, and the recommendation is that the study continue as planned.

2. CCDR S1415CD: *Pragmatic Trial to Evaluate a Guideline-Based Colony Stimulating Factor Standing Order Intervention and to Determine the Effectiveness of Colony Stimulating Factor Use as Prophylaxis for Patients Receiving Chemotherapy with Intermediate Risk for Febrile Neutropenia – Trial Assessing CSF Prescribing Effectiveness and Risk (TrACER).*

The DSMC evaluated the first planned interim analysis, and the recommendation is that the study continue as planned.

3. LEUKEMIA S1612: *A Randomized Phase II/III Trial of “Novel Therapeutics” Versus Azacitidine in Newly Diagnosed Patients with AML or High-Risk MDS, Age 60 or Older*

The DSMC appreciated the very useful discussion with the study chair and the CTEP representative at our San Francisco meeting. The DSMC expects to receive the proposed changes to the S1612 protocol that were discussed at the DSMC meeting over the next few weeks. The changes of interest are related to eligibility, treatment administration, safety monitoring and proposed sample size for an initial safety cohort prior to enrolling the full sample size. Once the DSMC has reviewed and confirmed that all the key elements are included in the amended protocol, the Committee will provide a letter of support, indicating our support of the study team reopening the S1612 trial.

"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."

4. LEUKEMIA S1318: *A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL, Relapsed/Refractory Philadelphia-Chromosome Positive (Ph+) ALL, and Philadelphia-Chromosome-Like Signature (Ph-Like) ALL (Newly Diagnosed or Relapsed/Refractory) with Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF).*

The DSMC is supportive of the primary endpoint of the Ph- cohort to be changed from 3-year overall survival rate to 1-year overall survival rate. However, we recognize that CTEP needs to give their approval of this proposed change. We expect the study team will pursue that amendment with them.

5. 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 approves of the concept of a one hundred patient case-control study as was described in their proposal to evaluate whole exome sequencing using FFPE biopsies and circulating tumor DNA over time. The study team has permission to submit a TM concept through the usual review channels at SWOG and the NCI to gain full permission to conduct this study.

6. LUNG S1400: *A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer.*

The DSMC gives permission for the study team to conduct a stratified analysis of outcomes based on class of drug (i.e., targeted therapy, immune checkpoint inhibitor therapy or chemotherapy) in the pooled Lung Map trials S1400A, S1400B, S1400C, S1400D, S1400E, S1400G, S1400K and S1400I. The DSMC also strongly encourages the timely publication of the three most recently completed trials (G, K and I) in addition to this analysis.

7. GASTROINTESTINAL S1505: *A Randomized Phase II Study of Perioperative mFOLFIRINOX versus Gemcitabine/nab-Paclitaxel as Therapy for Resectable Pancreatic Adenocarcinoma.*

The DSMC gives permission for the study team to conduct the two analyses that they proposed in their report submitted to the DSMC; namely, i) Initial Results on Eligibility and Pre-op Chemotherapy Experience, and ii) Initial Results on Surgical Resection after Preoperative Chemotherapy. No post-surgical outcomes are to be reported until the primary results are mature.

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

NCTN Studies:

Breast: S1007, S1416, S1418, S1706

Gastrointestinal: S1613, S1815

Genitourinary: S0931, S1011, S1216, S1500, S1602, S1605, S1802, S1806

Leukemia: S1712

Lung: S1400, S1400F, S1400K, S1701, LUNGMAP, S1900A

Lymphoma: S1608

Melanoma: S1616, S1801

Myeloma: S1211

NCORP Studies:

Prevention/Epidemiology: S0820

Symptom Control/Quality of Life: S1600, S1614

Survivorship: S1316, S1501

Cancer Care Delivery Research: S1703

The next DSMC meeting is expected to be held tentatively on Friday, October 4, 2019 at 7:30 am CT, coinciding with the SWOG Group Meeting in Chicago. Details will be confirmed later.