
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 31, 2016
RE: SWOG DSMC –Review of Pre-specified Safety Analysis for S1313

Gastrointestinal S1313 – A Phase IB/II Randomized Study of Modified Folfirinox + Pegylated Recombinant Human Hyaluronidase (PEGPH20) versus Modified Folfirinox Alone in Patients with Good Performance Status Metastatic Pancreatic Carcinoma.

After reviewing the adverse event summary tables by arm, statistical analysis details, clinical input from the S1313 study team, and the content of the most recent CTEP-approved amendment for this study regarding low molecular weight heparin as prophylaxis for thromboembolic events, the DSMC recommends the study continue as planned. We do, however, request that a representative from the study leadership plan to attend the open session of the next DSMC meeting in order to discuss the current status of this study in more detail.