Recommendations of the ECOG Data Monitoring Committee, May 10, 2010

The Data Monitoring Committee (DMC) of the Eastern Cooperative Oncology Group met at the ECOG Coordinating Center on May 10, 2010 to review all ongoing phase III studies coordinated by ECOG. This report is being provided to ECOG investigators and to other participating groups for transmission to their local IRBs.

The DMC review included examination of aggregated adverse event data by treatment arm for each study, consideration of whether studies were making adequate progress towards completion, and, when appropriate, examination of interim outcome results. Results from other studies and other recent literature that might be relevant to the research were also considered. The complete ECOG DMC policy is available at http://www.ecog.org/general/monitoring.html. The adverse event data reviewed by the DMC is summarized in the interim reports for the June 2010 ECOG Group Meeting. Local investigators should make copies of the relevant reports available to their local IRBs. ECOG members can obtain these reports from http://www.ecog.org/agenda. Copies are also provided to the operations offices of other participating groups. If an IRB requires additional information, please contact Mary Steele at the ECOG Operations Office at (617) 632-3610.

The DMC accepted the reports on E1105, E1208, E1305, E1505, E1697, E1A05, E1A06, E3F05, E2805, E2905, E3805, E4203, E5202, and E5204 without discussion, recommending that these studies continue without modification. The DMC recommendations on the other studies are listed below.

E2902 - A Phase III Study of Farnesyl Transferase Inhibitor R115777 in AML Patients in Second or Subsequent Remission or in Remission after Primary Induction Failure. *Study Chair: Dr. Selina Luger. Statistician: Xiaopan Yao.*

Recommendation: The sixth planned interim analysis of DFS was presented. Protocol criteria for stopping were not met, and the DMC recommended that this study continue with blinded follow-up as planned.

E4402 - Randomized Phase III Trial Comparing Two Different Rituximab Dosing Regimens for Patients with Low Tumor Burden Indolent non-Hodgkin's Lymphoma. *Study Chair: Dr. Brad Kahl. Statistician: Fangxin Hong.*

Recommendation: The DMC reviewed the fifth planned interim analysis of the primary endpoint of time to rituximab failure. The DMC recommended that this study continue with follow-up as planned and that all reasonable action should be taken to obtain pathology materials and complete the central pathology review.

E5103 - A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast Cancer. *Study Chair: Dr. Kathy Miller. Statistician: Anne O'Neill.*

Recommendation: The DMC reviewed the updated data on cardiac toxicity. The DMC recommended that this study continue as planned. Intensive monitoring of cardiac toxicity will continue. The DMC also recommended longer-term cardiac follow-up with collection of cardiac symptoms from the E5103 Cardiac Toxicity CRF at 2 years after registration.

PACT1: Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning IndividuaLized Options for Treatment: The TAILORx Trial. *Study Chair: Dr. Joseph Sparano. Statistician: Robert Gray.*

Recommendation: The DMC reviewed the status and progress of this study and recommended that this study continue as planned.