



Cancer and Leukemia Group B
Central Office of the Chairman

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Trini Ajazi
Group Administrator

MEMORANDUM

Date: July 14, 2006

To: CALGB Principal Investigators and Lead CRAs

From: Trini Ajazi, Group Administrator

Re: Data and Safety Monitoring Board (DSMB) Statements

Attached, please find the listing of DSMB recommendations released after the June 16, 2006 DSMB meeting.

You may submit the DSMB statements to your IRB per local IRB guidelines.

CALGB DSMB Recommendations June 2006

Cancer Control and Health Outcomes

79809

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 79809 during a meeting on June 16, 2006. The DSMB recommends continued monitoring without modification.

Action: Recommendation accepted.

Leukemia Committee

9710

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 9710 during a meeting on June 16, 2006. The DSMB recommends continued monitoring without modifications, and release of the study population demographic data to the Leukemia Committee.

Action: Recommendation accepted.

19808

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 19808 during a meeting on June 16, 2006. The DSMB recommends continued monitoring without modifications.

Action: Recommendation accepted.

10201

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 10201 during a meeting on June 16, 2006. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

GI Committee

80101

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 80101 during a meeting on June 16, 2006. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

80303

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 80303 during a meeting on June 16, 2006. The DSMB recommends release the study data to the GI Committee and the study team. If the data are released as recommended, the DSMB does not plan

additional monitoring of information emerging from this trial. If the data are released and individual study patients assigned to bevacizumab elect to discontinue that agent, this should not be considered a protocol violation at the time of audit.

Action: Recommendation accepted. Participating investigators were notified of the study results via email broadcast on June 27, 2006. Investigators were informed that based on a protocol-specified interim analysis, the DSMB found that the results had crossed a futility boundary and therefore it is very unlikely that significant differences in overall survival will be shown between the treatment arms with further follow-up. All patients still on treatment were unblinded. For those patients receiving placebo, placebo is to be discontinued and treatment with gemcitabine continued. For those patients receiving bevacizumab, patients could continue with bevacizumab + gemcitabine if there is evidence of clinical benefit. These patients may also elect to continue with gemcitabine alone. A sample patient letter explaining the study results was provided.

80405

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 80405 during a meeting on June 16, 2006. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

Breast Committee

40101

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 40101 during a meeting on June 16, 2006. The DSMB recommends continued accrual and monitoring without modification.

Action: Recommendation accepted.

49907

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 49907 during a meeting on June 16, 2006. The DSMB recommends continued accrual and monitoring without modification.

Action: Recommendation accepted.

GU Committee

90202

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90202 during a meeting on June 16, 2006. The DSMB recommends continued accrual and monitoring without modifications. The study team was commended for their success in dramatically increasing study participation.

Action: Recommendation accepted.

90206

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90206 during a meeting on June 16, 2006. The DSMB recommends continued monitoring without modifications.

Action: Recommendation accepted.

90401

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90401 during a meeting on June 16, 2006. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

Lymphoma Committee

50303

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 50303 during a meeting on June 16, 2006. The DSMB recommends continued accrual and monitoring without modifications.

Action: Recommendation accepted.

Transplant Committee

100104

The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 100104 during a meeting on June 16, 2006. The DSMB recommends continued accrual and monitoring. The study team should be informed that study accrual during the next 2 quarters will be monitored closely, and strategies to improve accrual should be developed and implemented.

Action: Recommendation accepted.