



Cancer and Leukemia Group B  
CENTRAL OFFICE OF THE CHAIRMAN

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**MEMORANDUM**

Date: August 15, 2007

To: CALGB Principal Investigators and Lead CRAs

From: Kathleen S. Karas, Director of Protocol Operations

Re: Data and Safety Monitoring Board (DSMB) Statements

Attached, please find the listing of DSMB recommendations released after the June 22, 2007 DSMB meeting.

You may submit the DSMB statements to your institutional review board (IRB) per local IRB guidelines.

## **CALGB Data and Safety Monitoring Board Recommendations**

### **CANCER CONTROL**

79809 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 79809 during a meeting on June 22, 2007. The DSMB recommended continued monitoring without modification. All participating institutions should be advised to submit delinquent on-study and follow-up data to the CALGB Statistical Center.

Action: Recommendation accepted.

### **LEUKEMIA**

19808 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 19808 during a meeting on June 22, 2007. The DSMB recommended continued monitoring. The DSMB requested that the study statistician provide the DSMB with the number of patients randomized on the second randomization who are still receiving drug and the number who have discontinued drug for reasons other than disease relapse.

Action: Recommendation accepted.

### **TRANSPLANT**

100103 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 100103 during a meeting on June 22, 2007. The DSMB recommended continued accrual and monitoring. The study team should be advised of the need to consider strategies for augmenting accrual. Substantially more timely submission of toxicity data is necessary, especially given that a secondary endpoint of the study is treatment-related mortality.

Action: Recommendation accepted.

100104 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 100104 during a meeting on June 22, 2007. The DSMB recommended continued accrual and monitoring. Assuming the amendment revising the statistical section is accepted by CTEP and the CIRB, one year from now the DSMB will review the status of study accrual.

Action: Recommendation accepted.

### **GI**

80101 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 80101 during a meeting on June 22, 2007. The DSMB recommended continued accrual and monitoring without modifications.

Action: Recommendation accepted.

80405 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 80405 during a meeting on June 22, 2007. The study team is carefully monitoring toxicity

events, especially in light of the findings of the recently reported PACCE trial. The DSMB members are aware of differences between cetuximab and panitumomab as well as the available phase II data for the chemotherapy + bevacizumab + cetuximab regimen. The DSMB recommended continued accrual and monitoring. The DSMB requests an updated toxicity analysis in 3 months - or sooner if new grade 5 events occur - to be submitted to the DSMB via Drs. George and Green.

Action: Recommendation accepted.

## **GU**

90202 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90202 during a meeting on June 22, 2007. The DSMB recommended continued accrual and monitoring without modifications.

Action: Recommendation accepted.

90203 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90203 during a meeting on June 22, 2007. The DSMB recommended continued accrual and monitoring without modifications.

Action: Recommendation accepted.

90206 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90206 during a meeting on June 22, 2007. The DSMB recommended releasing the data set to the study team. The survival status of all patients on study should continue to be monitored.

Action: Recommendation accepted. Study results were released to participating investigators on July 9, 2007. A sample patient letter was distributed for use in notifying patients.

90401 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 90401 during a meeting on June 22, 2007. The DSMB recommended continued accrual and monitoring. The monthly toxicity update reports prepared by the study team should be provided to Drs. Green and George on a real time basis. The DSMB endorsed the study team's plan to broadcast directives regarding the use of primary prophylactic growth factors and careful assessment of performance status of potential participants.

Action: Recommendation accepted. The broadcast addressing these issues was broadcast to participating investigators on July 23, 2007.

## **LYMPHOMA**

50303 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 50303 during a meeting on June 22, 2007. The DSMB recommended continued accrual and monitoring without modifications.

Action: Recommendation accepted.

## **BREAST**

40101 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 40101 during a meeting on June 22, 2007. It was noted that the accrual rate over the past 6 months is less than 25% of predicted despite expansion of eligibility. The DSMB recommended continued accrual and monitoring without modifications at this time. The DSMB will further discuss the current accrual rate to the trial with the Breast Committee leadership via conference call.

Action: Recommendation accepted.

40302 The CALGB Data and Safety Monitoring Board (DSMB) reviewed protocol 40302 during a meeting on June 22, 2007. The DSMB recommended continued accrual and monitoring without modifications.

Action: Recommendation accepted.