Update #5
01/15/2012

CANCER AND LEUKEMIA GROUP B

PROTOCOL UPDATE TO CALGB 100701/BMT CTN 0804

PHASE II STUDY OF REDUCED-INTENSITY ALLOGENEIC STEM CELL TRANSPLANT FOR HIGH-RISK CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

Rituximab provided by Genetech and distributed by Biologics Inc.
Limited Access Study:
CALGB- and BMT CTN-Approved Allogeneic Transplant Centers

__X__ Revision	**__X__ Amendment**	**_____ Status Change**
_____ Change of participant(s)		_____ Activation
__X__ Editorial, administrative changes		_____ Closure
_____ Scientific changes **(IRB approval)**		_____ Suspension
__X__ Therapy changes **(IRB approval)**		_____ Reactivation
__X__ Eligibility changes **(IRB approval)**		
_____ Informed Consent changes **(IRB approval)**		
__X__ Other: Sample submission instructions clarified		

IRB review and approval of this update is required within 90 days. Expedited IRB review allowed. Sites should follow their local IRB recommendations.

REVISIONS/AMENDMENTS:

Schema Page 1 of 3 (page 3):

Under "Patient Eligibility", the following eligibility criterion has added to the Advanced Disease Cohort: "FISH showing deletion of 17p in ≥ 20% of cells (regardless of interval from initial therapy) either alone or in combination with other cytogenetic abnormalities."

Schema Page 2 of 3 (page 4):

Under the heading "Preparative Regimen 1 9see Section 9.2.1) + GVHD Prophylaxis Regimen 1 (see Section 9.3.1)", in Footnote "R", the second sentence has been removed (formerly, "The rituximab infusion may be moved up or back by as many as two days"). The rituximab infusion should follow the days provided.

Schema Page 3 of 3 (page 5):

Under the headings "Preparative Regimen 1 (see Section 9.2.1) + GVHD Prophylaxis Regimen 2 (see Section 9.3.2)", and "Preparative Regimen 2 (see Section 9.2.1) + GVHD Prophylaxis Regimen 2 (see Section 9.3.2)", in Footnotes "R", the second sentences have been removed (formerly, "The rituximab infusion may be moved up or back by as many as two days"). The rituximab infusion should follow the days provided.

Section 4.1.2 (Advanced Disease Cohort, page 15):

Section 4.1.2.1 has been added: "FISH showing deletion of 17p in ≥ 20% of cells (regardless of interval from initial therapy) either alone or in combination with other cytogenetic abnormalities." Sections 4.1.2.2 through 4.1.2.4 have been renumbered.

Section 4.11 (page 16):

The eligibility criterion has been added: "No history of Richter's transformation." The subsequent section has been renumbered.

Section 7.2 (Data Submission, page 20-21):

- Beneath the data submission table, Footnote * has been revised to remove reference to the Pathology Coordinating Office. This was originally included in error.
- Footnote ** has been removed.

Section 7.3.2 (Sample Submission, page 22):

- A new third paragraph has been added to this section to clarify the temperatures for specimen submission:

  "In the red top and lavender top lubes, ship the specimens cold (refrigerator temperature). In the green top tubes, ship the specimens at ambient temperature. If it is not possible to ship at two separate temperatures, then all tubes may be shipped cold. Frozen cold packs should NOT be used."
- Within the Leukemia Tissue Bank shipping address, "Attn.: CALGB 151101" has been corrected to "Attn.: CALGB 20802."

Section 9.2.1.3 (Rituximab, page 24):

The second sentence has been removed. The rituximab infusions should follow the days provided.

Section 9.2.2.4 (Rituximab, page 25):

The second sentence has been removed. The rituximab infusions should follow the days provided.

Replacement pages include the Cover Page (page 1), and pages 3-5, 15, 16, 20-22, 24 and 25.

ATTACH TO THE FRONT OF EVERY COPY OF THIS PROTOCOL

cc: BMT/CTN