SUMMARY OF CHANGES
Update: June 7, 2012
(Broadcast 6/7/12)

RTOG 0330, "A Pilot Phase II Study of Pre-Operative Radiation Therapy and Thalidomide (IND 48832; NSC 66847) for Low Grade Primary Soft Tissue Sarcoma or Pre-Operative MAID/Thalidomide/Radiation Therapy for High/Intermediate Grade Primary Soft Tissue Sarcoma of the Extremity or Body Wall"

Study Chair: Burton L. Eisenberg, MD, 603-653-3614, Burton.L.Eisenberg@Dartmouth.edu

RTOG 0330 has been updated as follows:

Title page: The Principal Investigator’s phone number was corrected.
SUMMARY OF CHANGES
Amendment 4, Version Date: August 17, 2011
(Broadcast 8/23/11)

RTOG 0330, “A Pilot Phase II Study Of Pre-Operative Radiation Therapy And Thalidomide (IND 48832; NSC 66847) For Low Grade Primary Soft Tissue Sarcoma Or Pre-Operative MAID/Thalidomide/Radiation Therapy For High/Intermediate Grade Primary Soft Tissue Sarcoma Of The Extremity Or Body Wall”

Study Chair: Burton L. Eisenberg, MD, 603-653-3613, Burton.L.Eisenberg@Dartmouth.edu

RTOG 0330 has been amended as follows:

As mandated by CTEP, Sections 6.5, 7.5, and 7.6 have been amended to require the use of CTCAE, version 4 for grading of all adverse events reported via AdEERS as of October 1, 2011. All RTOG case report forms will continue to use CTCAE, v. 3.0.

Note: References to CTCAE, v. 3.0 remain in the protocol. These are appropriate, as treatment decision for patients enrolled on this study were based on that version.

Other Changes
Section 7.5.3: This section was amended as required by CTEP to instruct sites to report AML or MDS via AdEERS.
RTOG 0330, "A Pilot Phase II Study Of Pre-Operative Radiation Therapy And Thalidomide (IND 48832; NSC 66847) For Low Grade Primary Soft Tissue Sarcoma Or Pre-Operative MAID/Thalidomide/Radiation Therapy For High/Intermediate Grade Primary Soft Tissue Sarcoma Of The Extremity Or Body Wall"

Study Chair: Burton L. Eisenberg, MD, 603-653-3613, Burton.L.Eisenberg@Dartmouth.edu

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RTOG 0330 has been amended as follows:

Institutions may use pegfilgrastim (Neulasta®) rather than filgrastim (Neupogen®). Sections 7.1.1.6 and 9.1.6.1 and the risks associated with G-CSF in Appendix IA, the sample consent, were revised to reflect this change, and Section 7.4.6 was added.

Other Changes

Section 7.1.2.1: In the second table, the parameters in the column titled, "Platelets Nadir of Last Course", were revised to be consistent with platelet guidelines employed in a prior RTOG Sarcoma study, RTOG 95-14.

Section 7.1.3: In the first paragraph, the reference to thalidomide dose modifications was corrected from Section 7.1.4.1 to Section 7.1.3.1.

Section 7.4.5: The first sentence was replaced with a "NOTE" to be consistent with Section 7.4.6.

An amended protocol is available on the RTOG Web site, http://www.rtog.org
SUMMARY OF CHANGES
Amendment 2, Version Date: June 22, 2005

RTOG 0330, "A Pilot Phase II Study Of Pre-Operative Radiation Therapy And Thalidomide (IND 48832; NSC 66847) For Low Grade Primary Soft Tissue Sarcoma Or Pre-Operative MAID/Thalidomide/Radiation Therapy For High/Intermediate Grade Primary Soft Tissue Sarcoma Of The Extremity Or Body Wall"

Study Chair: Burton L. Eisenberg, MD, 603-653-3613, Burton.L.Eisenberg@Dartmouth.edu

RTOG 0330 has been revised as follows:

Title page: The 800 number for RTOG Headquarters was added.

Eligibility Checklist:
- Page 1, Question 16: “APPT” was corrected to “PT”. In the subquestion, “If no” was corrected to “If yes”.
- Page 3, last paragraph: “prior to calling” was amended to “prior to web registration” to be consistent with Section 5.0.

Section 3.1.7: Under “Laboratory Studies”, the required thyroid function tests were specified; this change also was made in Section 11.1.

Section 3.2: The section beginning “Concurrent or prior malignancies” was inadvertently not numbered. It has now been numbered 3.2.6, and the subsequent sections were appropriately renumbered.

Section 4.0: The MUGA scan or echocardiography was deleted from Section 4.3 and added as a required pretreatment evaluation in Section 3.1.7 to be consistent with Section 3.1.4. Corresponding changes were made in Section 11.1, footnote “f” and in Appendix I, under procedures done “Before treatment”.

Section 5.1.1: Two sentences, providing information to sites, were added to the last paragraph.

Section 6.5, “Radiation Adverse Event Reporting”: The prior text in Sections 6.5.1 through 6.5.4 was deleted. A sentence was added at the end of Section 6.5 referring sites to the adverse event requirements in Sections 7.5 and 7.6.

Section 7.1.3: In the third sentence, the phrase “7 days per week” was added for clarity.

Section 7.3.5: The second sentence was added to provide further information to sites.

Section 7.3.8: As mandated by NCI, the “Comprehensive Adverse Events and Potential Risks List (CAEPR)” for thalidomide was added, and the prior list of risks was deleted.

Section 7.5, “Adverse Events”, was amended to current RTOG standard.

Section 7.6, “AdEERS Expedited Reporting Requirements”, was added as mandated by NCI, replacing the prior adverse event reporting text (and subsequent sections were renumbered).

Section 10.2.1.4: The phrase, “with permission of David Lucas, MD, protocol pathology chair” was deleted, as it is unnecessary.

The following changes were made in Section 11.1 to clarify assessments during treatment:
- Footnote “h” was amended to clarify that only a monthly CBC is necessary for Cohort B patients “During XRT and Thal”;
- The pregnancy test was deleted from the last two columns of the table to indicate that a pregnancy test is not required in follow up after completion of thalidomide;
- Footnote “j” was added to clarify that physical examinations should be done weekly “During XRT and Thal”.
RTOG 0330, Amendment 2 (Continued)

Appendix IA, the sample consent: The risks associated with thalidomide were amended to be consistent with NCI’s CAEPR list in Section 7.3.8.

An amended protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
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Study Chair: Burton L. Eisenberg, MD, 603-653-3613, Burton.L.Eisenberg@Dartmouth.edu

RTOG 0330 has been revised as follows:

Title page: The 800 number for RTOG Headquarters was deleted, as it is no longer current. The number also was deleted in Sections 6.5, 7.5, and 7.5.3.

Section 7.4.1.1: The phrase, “to a final concentration of 2 mg/2ml”, was deleted, as Mesna is stable up to a concentration of 20 mg/ml.

Section 8.4.6: Amputation for any reason was redefined as “a local failure” to be consistent with Section 13.1.2.5.

Section 9.1.7: The word, “routinely”, was replaced by “prophylactically”.

Section 10.2.1.9: The email address for LDS Hospital was updated.

Section 10.4.3.3: The address for invoice submission was updated.

Section 12.0: The address for data submission was updated.

Section 12.1: The thalidomide treatment form was designated “SF” (versus “TH”).

The following changes were made to Appendix IA, the study consent:

- Under risks associated with thalidomide, four risks were re-classified:
  - “Decreased blood counts”; “Pain with urination”; and “Trouble breathing” were classified as Less Likely versus Likely, and “…rapid or irregular heartbeat” was classified as Less Likely, but Serious versus Likely;
  - Due to the re-classification, two risks, “Decreased healing” (under Less Likely) and “Rapid heartbeat” (under Less Likely, but Serious) were deleted as redundant.

- Under “What Other Options Are There?”, the second sentence was revised for clarity;

- Under “What Are The Costs?”, the phrase, “NCI sponsored/supplied agent(s)”, was deleted in the first and second sentence, as it is redundant.

Appendix IB, the tissue consent: In the first paragraph under “About Using Blood For Research”, the amount of blood per sample was revised from “less than a teaspoon” to “about 1 ½ teaspoonfuls”.

A revised protocol is available (no password required) on the RTOG Web site, http://www.rtog.org
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Study Chair: Burton L. Eisenberg, MD, 603-653-3613, Burton.L.Eisenberg@Dartmouth.edu

RTOG 0330 has been updated as follows:

Title page: The contact information for Dr. Kraybill was updated.

Section 7.5, “Adverse Events”, was updated to current RTOG standard text.

Section 10.0, “Tissue Banking/Central Review/Translational Research”: The name of the RTOG Tissue Bank was updated to “RTOG Biospecimen Resource” throughout this section. In addition, the following changes were made:

- Section 10.1.1: The location of the Biospecimen Resource was updated.
- Section 10.2.1.9: Addresses for shipment of materials were updated.
- Section 10.2.1.10: The heading was updated to “Reimbursement”, and the text was updated to current RTOG standard.
- Section 10.4.3.3: The “Attn” line was updated to “Clinical Trials Administration”.
- Section 10.5: The web address was updated.

Note: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page as “Update Date”.
RTOG 0330, "A Pilot Phase II Study Of Pre-Operative Radiation Therapy And Thalidomide (IND 48832; NSC 66847) For Low Grade Primary Soft Tissue Sarcoma Or Pre-Operative MAID/Thalidomide/Radiation Therapy For High/Intermediate Grade Primary Soft Tissue Sarcoma Of The Extremity Or Body Wall"

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RTOG 0330 has been updated as follows:

Section 12.1: The schedule for the Adverse Event Evaluation (AE) was updated to “With each TF or SF; in follow up with SF (or with F1 if thalidomide is discontinued) as indicated”.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page as “Update Date”.

An updated protocol is available on the RTOG website: http://www.rtog.org/
RTOG 0330, "A Pilot Phase II Study Of Pre-Operative Radiation Therapy And Thalidomide (IND 48832; NSC 66847) For Low Grade Primary Soft Tissue Sarcoma Or Pre-Operative MAID/Thalidomide/Radiation Therapy For High/Intermediate Grade Primary Soft Tissue Sarcoma Of The Extremity Or Body Wall"

Study Chair: Burton L. Eisenberg, MD, 603-653-3613, Burton.L.Eisenberg@Dartmouth.edu

RTOG 0330 has been updated as follows:

Section 7.1.3: In the last sentence of the section, the reference to dose modifications was corrected from “Section 7.1.4.1” to “Section 7.1.3.1”.

Section 10.2.1.9: The contact information for the RTOG Tissue Bank was updated.

Section 12.1: In the schedule for the Adverse Event Evaluation (AE), the phrase, “With each TF” was corrected to “With each SF”.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page as “Update Date”.

An updated protocol is available on the RTOG website: http://www.rtog.org/
SUMMARY OF CHANGES
Update: June 17, 2004

RTOG 0330, “A Pilot Phase II Study Of Pre-Operative Radiation Therapy And Thalidomide (IND 48832; NSC 66847) For Low Grade Primary Soft Tissue Sarcoma Or Pre-Operative MAID/Thalidomide/Radiation Therapy For High/Intermediate Grade Primary Soft Tissue Sarcoma Of The Extremity Or Body Wall”

Study Chair: Burton L. Eisenberg, MD, 603-653-3613, Burton.L.Eisenberg@Dartmouth.edu

RTOG 0330 has been updated as follows:

Eligibility Checklist, page 3: For database purposes, Question 5, concerning assent for patients < 18 years, was made Question 23, and other questions were appropriately renumbered.

Section 9.1.8: In the parenthetical phrase, “megase” was corrected to “Megace™”.

NOTE: This is an editorial/administrative change to the protocol. NCI now requires that these changes be documented on the protocol title page as “Update Date”.

An updated protocol is available (no password required) on the RTOG website: http://www.rtog.org/