SUMMARY OF CHANGES
Update: February 5, 2013
(Broadcast: February 5, 2013)

RTOG 1115, "Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer"

Study Chair: M. Dror Michaelson, MD, PhD, 617-726-1594, dmichaelson1@partners.org

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RTOG 1115 has been updated as follows:

Cover Pages: ECOG has endorsed the study. Dr. Vapiwala was added as the ECOG co-chair, and CTSU contact information was added.

SUMMARY OF CHANGES
Update: August 9, 2012
(Broadcast: August 9, 2012)

RTOG 1115, "Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer"

Study Chair: M. Dror Michaelson, MD, PhD, 617-726-1594, dmichaelson1@partners.org

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RTOG 1115 has been updated as follows:

Title Page: City and state added to Dr. Bruner's contact information.

Eligibility Checklist: Page 4, question 18 regarding medical oncologist's name was deleted; the subsequent questions were renumbered.

Sections 10.2, 10.3, and Appendix II: Updated for clarity regarding specimen collections.

Appendix I: Reference to prednisone was deleted from the third paragraph under "risk to the unborn child". Prednisone is not a study drug in this trial.

Appendix VI: Updated "kit contents" list.

Appendix VII: Updated instructions.

SUMMARY OF CHANGES
Update: May 2, 2012
(Broadcast: May 2, 2012)

RTOG 1115, "Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer"

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RTOG 1115 has been updated as follows:

The IND number for TAK-700 has been added in the following sections of the protocol:

- **Title Page** (below the title)
- **Section 7.5** (section title)

Section 7.10: The Investigator's Brochure for TAK-700 is posted on the RTOG web site (noted at the end of the section).

SUMMARY OF CHANGES
Update: May 1, 2012
(Broadcast: May 1, 2012)

RTOG 1115, "Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer"

Study Chair: M. Dror Michaelson, MD, PhD, 617-726-1594, dmichaelson1@partners.org

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RTOG 1115 has been updated as follows:

Title Page: Checked boxes added to indicate U.S. and Canadian participation only for this trial, in accordance with International Collaboration Early-notification Process (ICE caP) standards.

Eligibility Checklist: Page 5, question 25, *"less than or equal to"* sign inserted in place of "less than" sign.

Section 3.1.12: The screening calculated ejection fraction value was corrected from "greater than or equal to institutional upper limit of normal" to " *"greater than or equal to institutional lower limit of normal"*. Also, ECHO added in parentheses next to echocardiogram. Corresponding corrections made to question 10 on page 1 of the **Eligibility Checklist**.

Section 4.1.2: "Treatment" changed to *"registration"*.

Section 5.4.4: The pre-registration requirements text for non-Canadian international institutions was removed from the protocol, as this study is not open to participation for non-Canadian international institutions. The following section was renumbered.

Section 6.0: The timing for radiotherapy to begin was updated from "56 days +/- 7 days" to "*8-10 weeks",* as specified in Section 7.0. Corresponding update made to the **Schema** page.

Section 7.14: Detailed Biologics, Inc. distribution information for TAK-700 has been inserted into the protocol.

Section 10.2.2: For clarity, the instruction to send the specimens to the RTOG Biospecimen Resource was inserted in rows 2 and 3 of the summary table.

Section 10.3.5: For clarity, the instruction to send the specimens to the RTOG Biospecimen Resource was inserted in rows 3 to 5 of the summary table.

Section 10.4: Second sentence added to provide information regarding storage time for frozen specimens stored at -80°C (-70°C to -90°C). At the end of the section, sentence added regarding Appendix VII.

Section 12.0: Updated to include data submission details using Medidata Rave®.

Section 13.3.4: Corrected sample size numbers to read *"390 patients/195 patients per arm"*, for consistency with the quality of life substudy accrual number calculation after accounting for loss of enrollment losses, as specified elsewhere within the protocol.

Section 13.5.7.1: Per CTEP, the CDUS monitoring method was clarified (CDUS Abbreviated).

References: Updated to correspond with the references cited within the protocol.

Appendix II (Study Parameter Table): Pages 2 and 3, last row, the assessment time points were numbered for clarity.

Appendix VII (PBMC Preparation Instructions): Bottom of 2nd page, deleted “provided by RTOG Emory”.