SUMMARY OF CHANGES
Update: **July 26, 2012**
(Broadcast: July 26, 2012)

RTOG 1102, A Phase I Study of Induction Ganitumab (IND #113278) and Gemcitabine, Followed by Ganitumab, Capecitabine, and 3D-Conformal Radiation Therapy (3D-CRT) With Subsequent Maintenance Therapy for Locally Advanced Pancreatic Cancer

Study Chair: Christopher Crane, MD; 713-563-2340; ccrane@mdanderson.org

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RTOG 1102 has been updated as follows:

Title Page: The Document History table has been revised for this update.

Section 7.2.8:

- **Induction and concurrent therapy:** The number of vials for initial drug shipment of ganitumab has been increased from 10 to 14 to provide the necessary amount needed for completion of induction and concurrent therapy for the average participant, per the protocol.
- **Maintenance Therapy:** Reorder supply of ganitumab has been revised to now include a choice of 12 or 14 vials.

SUMMARY OF CHANGES
Amendment 1: **April 23, 2012**
(Broadcast: April 24, 2012)

RTOG 1102, A Phase I Study of Induction Ganitumab (IND #113278) and Gemcitabine, Followed by Ganitumab, Capecitabine, and 3D-Conformal Radiation Therapy (3D-CRT) With Subsequent Maintenance Therapy for Locally Advanced Pancreatic Cancer

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RTOG 1102 has been amended as follows:

Section 7.2.6: In the 2nd paragraph, the bilirubin parameters to assess adequate hepatic function prior to the administration of ganitumab was changed from "≤ 1.5 x institutional ULN" to "< 3.0 mg/dL" to be equivalent with the eligibility parameters in Section 3.1.6.6

Appendix I (Sample Consent Form)

- **"Risks and side effects related to ganitumab":** In response to the revised risks and discomforts section in the most recent version of the AMG 479 Investigators Brochure v 7.0, the ganitumab risk profile has been updated in its entirety

- **"Reproductive Risks"**: The timeframe for which female patients should not breastfeed after treatment with ganitumab has been adjusted in the 2nd sentence of the 2nd paragraph. The timeframe for which female patients should use birth control after treatment with ganitumab has been adjusted in the 3rd sentence of the 2nd paragraph.

Other Changes

Title Page: Amendment 1 was added to and the protocol version date was amended in the Document History table

Section 7.2.4: The 1st sentence of the 5th paragraph was revised with the updated location of the ganitumab Temperature Excursion Form on the RTOG website

Section 7.2.8: The 2nd paragraph was revised and the 3rd and 4th paragraphs added to clarify the drug distribution process of Ganitumab for patient specific shipments of induction and concurrent treatment and pooled study specific shipments of maintenance therapy; the header of the RTOG 1102 Drug Shipment Schedule was revised for clarity

Section 7.2.10: 1st paragraph was revised with information on where to obtain the RTOG accountability forms for the patient specific Induction and concurrent treatment and the pooled study specific maintenance therapy.

SUMMARY OF CHANGES
Update: **November 15, 2011**
(Broadcast: November 15, 2011)

RTOG 1102, A Phase I Study of Induction Ganitumab (IND #113278) and Gemcitabine, Followed by Ganitumab, Capecitabine, and 3D-Conformal Radiation Therapy (3D-CRT) With Subsequent Maintenance Therapy for Locally Advanced Pancreatic Cancer

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RTOG 1102 has been updated as follows:

Title Page: Kimberly Perez, MD has replaced Naimish B. Pandya, MD as a Medical Oncology Co-Chair