RTOG
RADIATION THERAPY ONCOLOGY GROUP

July 18, 2006

To: All RTOG Full, Affiliate, and CCOP member sites, ACOSOG, CALGB, ECOG, GOG, NCCTG, NCIC-CTG, NSABP, SWOG, and CTSU

From: Walter J. Curran, Jr., M.D.
RTOG Group Administrator

Re: Data Monitoring Committee Meeting Minute, June 16, 2006

All Radiation Therapy Oncology Group Phase III studies are monitored by the RTOG Data Monitoring Committee. The RTOG policy governing the responsibilities, composition, and operation of the DMC as well as the minutes from the DMC meeting can be found on the RTOG website at http://www.rtog.org/pdf_document/DMC_Manual.pdf.

Copies of the DMC meeting minutes should be made available to local Institutional Review Boards (IRBs).

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MINUTES
RTOG DATA MONITORING COMMITTEE
June 16, 2006

RTOG Committee Members:
Joseph Aisner, M.D. Chair
Walter J. Curran, Jr., M.D. (Ex Officio)
Marie Diener-West, Ph.D.
Boris Freidlin, Ph.D. (Ex Officio)
Eli Glatstein, M.D.
Gary Hudes, M.D.
Allison Martin, M.D. (Ex Officio) (via telephone)
Ann O'Mara, Ph.D., R.N. (Ex Officio) (via telephone)
Kenneth Rosenzweig, M.D.
Nagalingam Suntharalingam, Ph.D.
R. Suzanne Swann, Ph.D. (Ex Officio)

Other Attendees:
Mitchell Machtay, M.D.
Kathryn Winter, M.S.
Thomas J. Wudarski, M.S

Via Telephone:
Deborah Bruner, Ph.D.
Elizabeth Gore, M.D.

PLANNED INTERIM ANALYSIS

CCOP

0315 – A RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED PHASE III STUDY TO DETERMINE THE EFFICACY OF SANDOSTATIN LAR® DEPOT (OCTREOTIDE ACETATE) IN PREVENTING OR REDUCING THE SEVERITY OF CHEMORADIATION-INDUCED DIARRHEA IN PATIENTS WITH ANAL OR RECTAL CANCER (Study Chairs: Babu Zachariah, M.D., Jaffer Ajani, M.D., Clement Gwede, Ph.D., R.N., Lisa Chin, M.P.H., J.D.)

Kathryn Winter M.S. presented the second planned interim analysis of the primary endpoint per the statistical analysis plan in the protocol. The study was activated on October 31, 1994. The study sample size was 226 and the patient accrual was 233, as of the date the study closed, 2/24/2006. The analysis indicated that the current data do not indicate a statistically significant reduction in grade 2+ diarrhea, therefore the recommendation is that the study should not be reported at this time. Final analysis will occur when all patients have been followed for a minimum of three months.

The DMC concurred with Ms. Winter's recommendation not to report at this time.

The Group Chair concurred with this recommendation.

SPECIAL REPORTS FOR ACCRUAL ISSUES

Breast

9804 – Phase III of Observation +/_ Tamoxifen vs. RT +/- Tamoxifen for Good Risk Duct Carcinoma In-Situ (DCIS) of the Female Breast

The DMC recommended that the study close since the accrual targets set at the January 2006 DMC meeting were not met. Follow-up for patients should continue for six (6) years for safety and toxicity related to the administration of Tamoxifen.

Lung
0214 – A Phase III Comparison of Prophylactic Cranial Irradiation vs. Observation in Patients with Locally Advanced NSCLC

The DMC recommended that the study remain open and that the following revised accrual targets should be imposed: twelve (12) cases per month by the end of 2006 with an increase to fifteen (15) cases per month by the end of May 2007.

The RTOG Group Chair concurred with the DMC's recommendations for the studies covered by the Special Reports for Accrual Issues.

RTOG OPEN PHASE III TRIALS: ACCRUAL AND TOXICITY REVIEWS

Brain
9813 - RT + Temozolomide vs. RT and BCNU for Anaplastic Astrocytoma and Mixed Anaplastic Oligoastrocytoma (Astrocytoma Dominant)

0320 - WBRT +SRS vs. WBRT + SRS + Temozolomide and WBRT + SRS + Erlotnib in Patients with NSCLC and 1-3 Brain Metastases

0525 - Conventional Adjuvant Temozolomide vs. Dose-Intensive Temozolomide in Patients with Newly Diagnosed Glioblastoma

H&N
0421 - Concurrent Re-Irradiation and Chemotherapy versus Chemotherapy Alone for Locally Recurrent, Previously Irradiated Head and Neck Cancer

0522 - CRT+/- C225for Advanced H&N Cancer

GU
0126 - High Dose 3D-CRT/IMRT vs. Standard Dose 3D-CRT/IMRT in Patients Treated for Localized Prostate Cancer

0232 – Combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy vs. Brachytherapy Alone for Selected Patients with Intermediate-Risk Prostatic Carcinoma

0415 – Hypofractionated 3D-CRT/IMRT vs. Conventionally Fractionated 3D-CRT/IMRT in Patients with Favorable-Risk Prostate Cancer

0521 - A Phase III Protocol of Androgen Suppression (AS) and 3DCRT/IMRT vs. AS and 3DCRT/IMRT Followed by Chemotherapy with Docetaxel and Predeisone for Localized, High-Risk Prostate Cancer

Lung
0412 - Preoperative Chemotherapy Versus Preoperative Concurrent Chemotherapy and Thoracic Radiotherapy Followed by Surgical Resection and Consolidation Chemotherapy in Favorable Prognosis Patients with Stage IIIa (N2) Non-Small Cell Lung Cancer

CCOP
0518 - Efficacy of Zometa for the Prevention of Osteoporsis and Associated Fractures in Patients Receiving RT and Long Term LHRH Agonists for High-Grade and/or Locally Advanced Prostate cancer

The DMC concluded that there was no need to modify any of these protocols as a result of unexpected or excessive toxicity. The DMC expressed their concern about the accrual to date for RTOG 0412, 9813, and 0320.

RTOG CLOSED PHASE III TRIALS: REVIEW OF TOXICITY

H&N
9512 - HX vs. STD FX in T2 Squamous Cell Carcinoma of the Vocal Cord

0129 - CRT (SFX vs. AFX-C) for Advanced H&N Cancer

GU
9408 - Endocrine Therapy Used as a Cytoreductive and Cytostatic Agent Prior to RT in Good Prognosis Locally Confined Adenocarcinoma of the Prostate

9601 - RT with or without Casodex in Patients with PSA Elevation Following Radical Prostatectomy for pT3N0 Carcinoma of the Prostate

9902 - Androgen Suppression *(AS)* & RT vs AS & RT followed by CT with Paclitaxel, Estramustine, & Etoposide (TEE) for Localized High-Risk Prostate Cancer

9910 - Duration of Neoadjuvant Total Androgen Suppression (TAS) + RT in Intermediate Risk Prostate Cancer

CCOP
0122 - Double Blind Study of Nutritional Intervention for Cancer Cachexia Using JUVEN® Nutritional Supplement

0215 – Treatment of ED in Patients Treated with Neoadjuvant Androgen Suppression and RT for Prostate Cancer: Impact on Patient and Partner QOL

The DMC concluded that there were no unexpected or excessive toxicity issues for these studies.

The next DMC meeting is scheduled for:
Wednesday January 17, 2007
9:00 am to 2:00 pm
ACR/RTOG Headquarters