



September 6, 2016

Norman Wolmark, MD, Walter Curran, MD, Philip DiSaia, MD
Co-Chairs, NRG Oncology Group
1600 John F. Kennedy Boulevard - Four Penn Center Suite 1020
Philadelphia, PA 19103

Dear Drs. Wolmark, Curran, and DiSaia:

The Clinical Investigations Branch of the Cancer Therapy Evaluation Program (CTEP) has reviewed your accrual for the phase III study GOG-0277, "*A Phase III Randomized Trial of Gemcitabine (NSC# 613327) Plus Docetaxel (NSC# 628503) Followed by Doxorubicin (NSC# 123127) Versus Observation for Uterus-Limited, High Grade Uterine Leiomyosarcoma.*"

An exception to the "Early Stopping Rules for Phase 3 Trials Due to Slow Accrual" under the NCTN Program was made for the NRG phase 3 trial, GOG-0277 in 2014. The exception consisted of reviewing the study at the end of Quarter 11 and if the study was accruing less than 7 patients a quarter, the study would be closed. CTEP reviewed the accrual at the end of Quarter 11 and the study enrolled 1 patient or 11.1% of the projected accrual (9 patients) during Quarter 11, 2 patients or 22.2% of the projected accrual during Quarter 10, and 1 patient or 11.1% of the projected accrual during Quarter 9. GOG asked for another exception to continue enrollment to this study at that time.

CTEP granted a second exception and allowed the study to remain open with the mandate for accrual of 35 patients per year, with the first year from 1 July 2015 to 30 July 2016, or the trial would be administratively closed by CTEP. The accrual reported to CTEP for this specified time frame was 13 patients, 37% of the required 35 patients.

CTEP is now requiring that study GOG-0277 be closed within 10 business days of the date of this letter (i.e., by close of business on Tuesday, September 20, 2016, per the *Early Stopping Guidelines* policy and the previous extensions given for this study). No further appeals will be considered. If for any reason NRG cannot comply with this request within the specified time-period because of administrative or operational issues, please notify me as soon as possible.

Sincerely,

Meg Mooney, MD
Chief, Clinical Investigations Branch, Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis, National Cancer Institute

cc: *Jeff Abrams, MD* *Martee Hensley, MD*
Elise Kohn, MD *Virginia Filiaci, Ph.D.*
Boris Freidlin, PhD *Joe Costantino, Ph.D.*
Ed Korn, PhD *Laura Reese*
Larry Rubinstein, PhD *Kia Neff*
Julie Kardell *Sharon Hartson Stine*
Robert Mannel, MD