A Phase III Randomized Study of Image Guided Conventional (60Gy/30fx) vs Accelerated, Hypofractionated (60Gy/15fx) Radiation for Poor Performance Status Stage II and III NSCLC Patients – An Interim Analysis

P. Iyengar¹, K. D. Westover¹, L. E. Court², M. K. Patel³, A. T. Shivnani⁴, M. W. Saunders⁵, Y. Li⁶, J. Y. Chang⁷, A. Gao⁸, C. Ahn¹, H. Choy⁹, and R. D. Timmerman¹

¹University of Texas Southwestern Medical Center, Dallas, TX, ²Department of Radiation Physics, The University of Texas MD Anderson Cancer Center, Houston, TX, ³Baylor Scott & White Texas A&M Radiation Oncology, Temple, TX, ⁴Texas Oncology, Dallas, TX, ⁵US Oncology, Tyler, TX, ⁶The University of Texas Health Science Center San Antonio, San Antonio, TX, ⁷Department of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX, ⁸UT Southwestern Medical Center, Dallas, TX, ⁹Princess Margaret Cancer Centre, Toronto, ON, Canada
• Patients with stage II and III NSCLC who cannot receive standard of care surgery or chemotherapy + radiation due to co-existing medical comorbidities or poor performance status have limited outcomes with conventionally fractionated radiation alone.

• We previously completed a phase I dose escalation study that demonstrated no increased toxicity in treating this patient population to doses reaching 60Gy in 15 fractions, which is half the number of radiation treatments as a standard course.
Fundamentally, we aim to determine if accelerated, hypofractionated radiation therapy can improve survival while halving treatment time in poor performing stage II/III NSCLC patients who cannot receive surgery or radiation + chemotherapy.
Method

- Patients with stage II NSCLC not candidates for surgery or stage III NSCLC not candidates for chemoradiation due to diminished PS (Zubrod PS 2 or greater)
- Randomization to conventional RT regimes of 60-66Gy/30-33fx or accelerated, hypofractionated RT of 60Gy/15 fx.
- Overall survival (OS) was the primary endpoint. Secondary endpoints included toxicity assessment, progression free survival (PFS), quality of life and cost effectiveness.
- Chemotherapy was permissible sequentially either as induction or in the adjuvant setting.
- The study was open at 15 institutions across the state of Texas and funded by the Cancer Prevention and Research Institute of Texas.
Results

• 60 patients have been enrolled on the study (28 to Arm A and 32 to Arm B), with a median age of 68y in both cohorts.

• 53/60 patients presented with stage III disease, 7/60 with stage II.

• 48/60 patients were evaluable due to adequate length of follow-up (24 months). 56% of patients (27/48) were alive at last follow-up.
Results

• By Kaplan-Meier analysis, median OS for the 48 patients evaluable was 14 months, with no statistical difference between conventional vs hypofractionated radiation treatment arms.

• PFS was 11.5 months with again no statistical difference between treatment arms.

• Grade 3 or higher toxicity was less in the experimental arm at this time.
Conclusions

• A curative approach with accelerated, hypofractionated radiation alone with similar OS and PFS to conventional radiation in a population of poor PS patients, with limited grade 3-5 toxicity, and a treatment course of half the time.

• Completion of this study will potentially change the paradigm of treatment of poor PS stage III NSCLC patients who cannot receive chemoradiation.