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RTOG/NRG 1115 Quality of Life of Phase III Dose Escalated Radiation Therapy (RT) and Standard Androgen Deprivation Therapy (ADT) with GnRH Agonist vs. Dose Escalated RT and ADT with GnRH Agonist and Orteronel (TAK-700) for Men with High-Risk Prostate

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bladder volume reduced DIL coverage (p=0.03, plan 1 vs 2), and prostate coverage (p= 0.03, plan 2 vs 3). Bladder filling was associated with fraction number, fraction 1 being higher than the other 4 (all p-values < 0.02). Treatment time on table was associated with change in bladder filling (p=0.01) and after accounting for this, the associations between change in bladder filling and fraction number were weaker. At a median follow-up of 9 mo, the maximum reported toxicity was G2 GU (n=2) and G2 GI (n=1). The median change in IPSS was 3.5.

Conclusion: SBRT with focal boosting of the DIL on the MRL with daily adaptive planning is feasible and results in excellent planned and delivered dosimetry and acceptable toxicity. Intra-fractional bladder filling may impact target coverage. When considering focal boosting with SBRT, adaptive planning with MRL may provide the greatest confidence for delivering the prescribed dose with least normal tissue exposure.

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RTOG/NRG 1115 Quality of Life of Phase III Dose Escalated Radiation Therapy (RT) and Standard Androgen Deprivation Therapy (ADT) with GnRH Agonist vs. Dose Escalated RT and ADT with GnRH Agonist and Orteronel (TAK-700) for Men with High-Risk Prostate

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Purpose/Objective(s): Quality of life (QOL) was assessed with the hypothesis that QOL and fatigue scores would not differ significantly between the ADT + RT (Arm A) and the experimental group receiving ADT + RT + oreteronel (Arm B).

Materials/Methods: In both arms, ADT with GnRH agonist was given for 24 mos, and dose escalated RT started 8-10 wks after initiation of ADT. In Arm B, oreteronel was given BID for 24 mos. QOL was measured with Expanded Prostate Cancer Index Composite (EPIC) and EQ-5D global QOL assessment. EPIC has 4 domains: bowel, urinary, sexual, and hormonal. EQ-5D index score was calculated using health states obtained from 5 dimensions, and a visual analog score (VAS). For EPIC, EQ-5D index and VAS, higher scores indicate better QOL. Fatigue was measured by the 7-item Patient-Reported Outcome Measurement Information System (PROMIS) short form. Total score is standardized into a T-score with mean of 50 and standard deviation of 10 with higher score representing more fatigue. Change scores, calculated as follow-up minus baseline, were compared between arms. Longitudinal analysis using repeated measures mixed effects models was conducted (prior to ADT [baseline], one wk prior to starting RT, last wk of RT, and 1 and 2.5 yrs after initiation of therapy).

Results: Of 231 eligible patients, 196 consented to QOL, 102 on Arm A and 94 on Arm B. Compliance prior to start of RT and end of RT was 83%. At 1 and 2.5 yrs, 80% and 62% of pts, respectively, completed the EPIC. There were no differences between any EPIC domain between arms from the start of RT through the end of follow-up. Men on oreteronel had a significantly greater decline in bowel score prior to starting RT then control patients (-6.12, 95% confidence interval [CI]: -9.24, -3.01 vs. -1.93, 95% CI: -4.48, 0.63, respectively, p=0.038). Arm B patients also had a statistically significant and clinically meaningful worse change in urinary score vs control from baseline to pre-RT (-2.33, 95% CI: -5.02, 0.36 vs. 1.38, 95% CI: -1.07, 3.83, respectively, p=0.043). No other timepoints were significant. The only sig. between arm difference in EPIC sexual and hormonal scores was also at pre-RT in favor of Arm A over Arm B; p=0.024 and p=0.0024 respectively). Fatigue was also greater in the oreteronel patients prior to starting RT (3.81, 95% CI: 1.88, 5.74 vs. 1.18, 95% CI: -0.23, 2.60, p=0.028).

Conclusion: The addition of oreteronel to RT and ADT resulted in greater declines in QOL prior to the start of RT but did not result in significant differences at any other time points. Although oreteronel development has been halted, the QOL results are encouraging for other drugs in this class that remain under investigation. In ongoing prospective trials, QOL impacts should be measured in conjunction with changes in clinical outcome and survival. This project was supported by grants UG1CA189867, U10CA180868, U10CA180822 from the National Cancer Institute and Takeda Pharmaceutical.

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Prognostic Utility of (18)F-Fluciclovine Positron Emission Tomography (FACBC) in Biochemically Recurrent (BCR) Prostate Cancer (PCa) Treated with Salvage Radiotherapy

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Purpose/Objective(s): Patients with a biochemical recurrence after definitive radiotherapy or prostatectomy often undergo imaging to localize recurrent disease prior to salvage treatment. FACBC is a commonly utilized scan for this, but little is known about the prognostic utility of imaging metrics derived from FACBC scans in this setting.

Materials/Methods: This single-center retrospective study included 167 patients (pts) who had FACBC for BCR between 10/2017-10/2019. Clinical, pathological, imaging, and treatment data were collected by chart review.