5076 **Poster Session**

Survival analysis of the randomized phase II trial to investigate androgen signaling inhibitors with or without androgen deprivation therapy (ADT) for castration-sensitive prostate cancer: LACOG 0415.

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Background: LACOG 0415 is a phase II, open-label, clinical trial evaluating ADT-free alternatives for advanced castration sensitive prostate cancer (CSPC). **Methods:** Patients with locally advanced, high-risk biochemical recurrence or metastatic CSPC were randomized (1:1:1) to receive ADT with abiraterone acetate plus prednisone (ADT+AAP), apalutamide alone (APA), or apalutamide with AAP (APA+AAP). The primary endpoint of the trial was the proportion of patients who achieved PSA≤0.2 ng/mL level at week 25. Patients without disease-progression and with clinical benefit after week 25 were allowed to maintain treatment at the discretion of physicians. Herein, we presented the outcomes of 2 year-overall survival (2y-OS) and time-to-treatment failure (TTF). The time-to-event endpoint was estimated by Kaplan-Meier method and compared by stratified log-rank test. **Results:** 128 patients were randomized to the ADT+AAP (n = 42), APA (n = 42), and APA+AAP (n = 44) arms. At week 25, PSA≤0.2 ng/mL was observed in 75.6% (95%CI 59.7%-87.6%), 60.0% (95%CI 43.3%-75.1%), and 79.5% (95%CI 63.5%-90.7%) of patients in the ADT+AAP, APA, and APA+AAP arms, respectively. 110 patients continued treatment after week 25. At the 2-year visit, 80 (62.5%) patients remained on the study medication. Median TTF was 24.0 months (95%CI 23.3 - 24.0) with ADT+AAP, 24.0 months (95%CI not estimated) with APA, and 24.0 months (95%CI 13.0-24.0) with APA+AAP. The main reasons for treatment discontinuation were disease progression (n = 8, 6.3%), toxicity (n = 10, 7.8%), death (n = 6, 4.7%), withdrawal (n = 4, 3.1%), and other (n = 19, 14.8%). The estimated proportion of patients who were alive at 2 years (2y-OS rate) was 92.5% (95%CI 84.3-100) with ADT+AAP, 87.9% (95%CI 77.9-97.8) with APA, and 92.7% (95%CI 84.8-100) with APA+AAP (p = 0.5926). 2y-OS was 92.9% (95% CI 85.3 - 96.2) in patients with PSA ≤ 0.2 ng/mL at week 25, while 2y-OS was 85.0% (95% CI 72.9-97.1) in patients with PSA > 0.2 ng/mL at week 25 (p = 0.1250). **Conclusions:** Patients with advanced CSPC treated with ADT+AAP, APA, or APA+AAP had high rates of PSA response and favorable 2y-OS. PSA ≤ 0.2 ng/mL at week 25 seems to be a surrogate prognostic predictor of OS in advanced CSPC. In the overall sample, patients with PSA ≤ 0.2 ng/mL at week 25 had higher 2y-OS rate than those with PSA > 0.2 ng/mL at week 25 (92.9% vs. 85.0%), however without statistical significance. Clinical trial information: NCT02867020. Research Sponsor: Janssen-Cilag.