## 855PD Docetaxel for hormone-naïve prostate cancer (PCa): Results from long-term follow-up of non-metastatic (M0) patients in the STAMPEDE randomised trial

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**Background:** STAMPEDE previously reported that adding upfront docetaxel (Doc) improved overall survival (OS) for locally advanced and metastatic patients (pts) starting long-term androgen deprivation therapy (ADT). We report the long-term outcomes for M0 pts using metastatic progression-free survival (mPFS) as primary outcome, previously shown to be a surrogate for OS in M0 pts.

**Methods:** Standard-of-care (SOC) was ADT +/- radical radiotherapy (RT) to the prostate. 460 SOC and 230 SOC+Doc pts were recruited with 2:1 randomised stratified allocation. Standard survival intention-to-treatment analysis methods used Cox regression models adjusted for all stratification factors, with emphasis on restricted mean survival time (RMST) for non-proportional (non-PH) hazards. There was 70% power (2-sided $\alpha = 0.05$) to detect HR = 0.70 for mPFS (= new metastases, skeletal related events or PCa death). Secondary outcome measures included failure free survival (FFS) and progression free survival (PFS = mPFS or locoregional progression).

**Results:** Median follow-up was ~6.5yr compared to ~3.5yr when last reported, with 142 mPFS events (a 54% increase) on SOC. There was no good evidence of an advantage of SOC+Doc over SOC on mPFS (HR = 0.89, 95% CI 0.66-1.19, P = 0.425); with 5yr mPFS 82% in SOC+Doc vs. 77% SOC. Secondary outcomes showed evidence that SOC+Doc improved FFS (HR = 0.70, 95% CI 0.55-0.88, P = 0.002) and PFS (non-PH P = 0.033, RMST difference=5.8 months, 95% CI 0.5-11.2, P = 0.031). There was no good evidence of a benefit of SOC+Doc on OS (125 SOC deaths; HR = 0.88, 95% CI 0.64-1.21, P = 0.442). There was no evidence that SOC+Doc increased late toxicity compared to SOC: after 1yr, G3-5 toxicity reported for 29% SOC and 30% SOC+Doc. The impact of SOC RT (nominated prior to randomisation) with and without SOC+Doc will also be detailed by subgroup.

**Conclusions:** There is robust evidence SOC+Doc improves FFS and PFS (which we have previously shown increases Quality Adjusted Life Years). There is however no good evidence that this translates into benefit for longer-term outcomes (OS or mPFS). The benefits of upfront SOC+Doc for improved FFS and PFS with no excess late toxicity may contribute to treatment discussions.

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