TPS401

**Background:** The detection of androgen-receptor splice variant 7 (AR-V7) mRNA transcript in circulating tumor cells (CTCs) of progressive metastatic castration-resistant prostate cancer (mCRPC) patients is associated with resistance to abiraterone and enzalutamide. This finding was validated by other studies that found no association between the presence of AR-V7 transcripts and response to both docetaxel and cabazitaxel. The results suggest that AR-V7 could represent a biomarker to guide treatment selection in mCRPC. However, data in Asian population is limited. This multinational study aims to prospectively investigate the incidence and prevalence of ARV7 in Asian mCRPC patients. This is also the first study to evaluate 3 different detection platforms and help provide guidance on which will be the best platform to carry forward in terms of clinical utility.

**Methods:** 101 Asian subjects with histologically confirmed mCRPC whom are going to be treated with AR-directed therapies (abiraterone, enzalutamide) or taxane chemotherapy (docetaxel) will be enrolled from Singapore, Malaysia, Thailand, Hong Kong and Japan. Subjects will be excluded if they plan to receive additional concurrent anticancer therapies. Peripheral-blood samples will be obtained at baseline and at the time of progression. We will use 3 methods to analyse the samples: (i) CTC enrichment platform followed by automated immunofluorescent staining for DNA, cytokeratins, CD45 (lymphocyte common antigen), and AR-V7; (ii) CTC enrichment platform followed by reverse-transcription polymerase chain reaction analysis; and (iii) the AdnaTest platform for molecular characterization of CTCs. Subjects will be followed up to 2 years. The clinical outcomes of AR-V7-positive and AR-V7-negative patients will be compared. PSA response rates will be compared using the Fisher exact test. Time-to-event outcomes (PFS, OS) will be evaluated using Kaplan-Meier analysis, and survival time differences will be compared using log-rank test. Cox regression analyses will be used to assess the effect of AR-V7 status in predicting clinical outcomes. The study is in progress; 32 of 101 planned patients have been enrolled at the end of September 2017.