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Overall survival (OS) implications for patients with mCRPC through coverage and adoption of nuclear AR-V7 testing by healthcare systems

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Background: Nuclear-localized AR-V7 testing of circulating tumor cells (CTCs) has been validated as a predictive biomarker of chemotherapy response and ARSI non-response in $2^{\rm nd}+$ line therapy for metastatic castration-resistant prostate cancer (mCRPC). A validation study showed that AR-V7(+) pts have improved OS with taxane chemotherapy, and AR-V7(-) pts have improved OS with ARSi. We assessed the effect of AR-V7 testing on OS when generalized to non-trial clinical settings, as found in third-party US healthcare systems.

Methods: The causal effect of treatment and nuclear AR-V7 status on OS was estimated from risk-adjusted hazard rates of the MSK, ICR, LHS validation study. Therapeutic strategies assessed were (1) taxanes only, (2) ARSi only, (3) current US utilization rate of ARSis, and (4) nuclear AR-V7-guided treatment. Quality of life adjustments were extracted from meta-analysis of large cohort studies. We applied US utilization rate of consecutive ARSi administration (abiraterone after enzalutamide, or enzalutamide after abiraterone) and compared to switching with taxane-based chemotherapy (docetaxel after enzalutamide).

Results: The following table shows OS, adjusted and unadjusted for quality of life, and treatment by strategy. The net effects on OS were robust to variation on the clinical effects, and on systems covariates, e.g., demographic, patient, and payer case-mix.

Table: 848P			
2nd line mCRPC therapy	% ARSi	OS (months)	Net OS gain
strategy		QALY (Unadj / Adj.)	(months) QALY
			(Unadj / Adj)
Only use taxanes	0%	19.2 / 12.2	-3.7 /-2.0
Only use ARSi's	100%	25.4 / 15.6	2.5 / 1.4
Current use of ARSi (US)	60%	22.9 / 14.2	- REF -
AR-V7 guided treatment	77%	27.3 / 16.7	4.4 / 2.5

Conclusions: Health outcome modeling of the validation data support that current use and access to 2nd ARSi therapy can improve OS of patients over strict use of taxane chemotherapy (+3.7mo OS). $2^{\rm nd}+$ line nuclear-localized AR-V7 guided treatment for men with progressive mCRPC provides higher OS than non-guided, almost doubling the gain (+4.4 mo OS) observed with current US utilization rate of ARSi versus taxanes only. Cost effectiveness analyses of the adoption/coverage of nuclear AR-V7 testing in healthcare systems is ongoing.

 $\label{legal entity responsible for the study: MSKCC.} Legal entity responsible for the study: {\tt MSKCC}.$

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