Abstract 5567: Olaparib in patients with prostate cancer with *BRCA1/2* inactivating mutations: Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study

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Background:

- TAPUR is a phase II basket study that evaluates anti-tumor activity of commercially available targeted agents in patients (pts) with advanced cancers with specific genomic alterations.
- **Results of a cohort of prostate cancer (PC) pts with germline or somatic *BRCA1/2* inactivating mutations treated with olaparib (O) are reported.**

Methods:

Study Design:

- **Eligible pts:** Advanced PC, no standard treatment (tx) options, ECOG PS 0-2, adequate organ function, measurable disease. Tx assigned according to pre-specified matching rules based on genomic tests selected by sites.
- Pts received O tablets or capsules dosed at 300 mg (n=16) or 400 mg (n=9), respectively, orally BID until disease progression. Tumor evaluations were performed at 8 and 16 wks then Q12 wks after tx initiation.
- **Primary endpoint:** Disease control (DC) defined as objective response (OR) or stable disease (SD) at 16+ wks per RECIST v1.1.
- **Secondary endpoints:** progression-free survival (PFS), overall survival (OS), and toxicity per CTCAE. Grade 3-5 adverse events (AEs) or serious adverse events (SAEs) at least possibly related to O are reported.

Statistical Methods:

- Simon's optimal two-stage design used to test null hypothesis of 15% DC rate vs. alternative of 35%. Power = 85%; 1-sided α = 10%.
- ≥7 of 28 pts must achieve DC to reject null hypothesis and consider tx worthy of further study.

Olaparib has anti-tumor activity in heavily pre-treated patients with prostate cancer with germline or somatic *BRCA1/2* inactivating mutations.

Future Direction: Findings consistent with recent studies of O in this pt population. Further study warranted.

Results:

- 29 male pts enrolled Aug 2016 to July 2019; 4 were ineligible and are excluded from all analyses; 20 pts (80%) had *BRCA2* mutation; 5 pts (20%) had *BRCA1* mutation
- **Demographics:** Median age: 65 y (range 40-90); Race: 80% White, 20% Black
- **Clinical characteristics:** 44% PS 0, 56% PS 1; 60% received ≥3 prior systemic regimens; 40% received 1-2 prior regimens
- **Outcomes:** 2 CR, 11 PR, 4 SD16+ (Table 1 and Figure 1). Time on O among pts with SD and OR is shown in Figure 2.
- **Safety:** 3 pts (12%) had ≥1 SAE or Grade 3-4 AE at least possibly related to O and consistent with previously reported AEs

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Table 1: Efficacy Outcomes (N=25)	
DC rate, % (90% CI)	68 (53, 77)
OR rate, % (95% CI)	52 (31, 72)
1 year OS, % (95% CI)	60.0 (36.5, 76.8)

Figure 1: OS and PFS in Pts with Advanced PC with *BRCA1/2* Inactivating Mutations Treated with O (N=25)

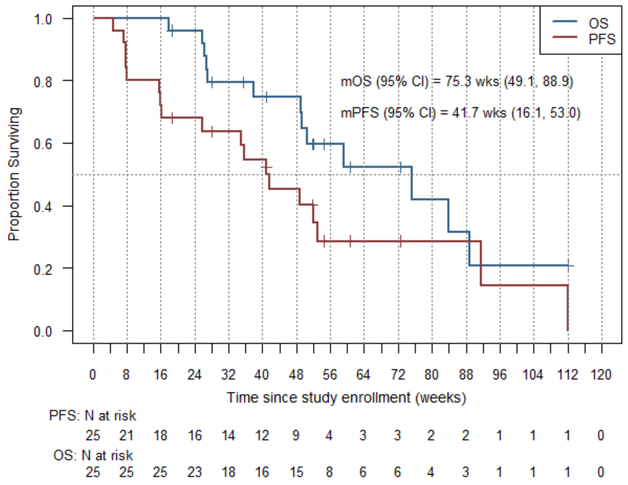

Figure 2: Time on Treatment in Pts with SD or OR (N=17)