Poster: #1654P

TAMARACK: Randomized Phase 2 Trial of the B7-H3–Targeting Antibody Drug Conjugate (ADC) Vobramitamab Duocarmazine (Vobra Duo) in Metastatic Castration-Resistant Prostate Cancer (mCRPC)

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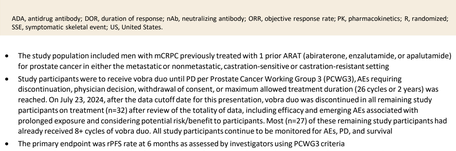
POSTER OBJECTIVES

- We present interim results of TAMARACK, an ongoing, randomized, open-label, global phase 2 trial (NCT05551117, CP-MGC018-03) assessing efficacy, safety, and tolerability of 2 dose levels of vobra duo (2.0 mg/kg and 2.7 mg/kg intravenously [IV] every 4 weeks [Q4W]) in study participants with mCRPC previously treated with 1 prior androgen receptor axis-targeted therapy (ARAT)
- Additionally, we present select, updated, final results from the mCRPC expansion cohort of the phase 1 study of vobra duo (NCT03729596, CP-MGC018-01)
- TAMARACK data are as of a cutoff date of July 9, 2024; data are from an ongoing study and are subject to change
- CP-MGC018-01 data are as of the final cutoff date of August 3, 2023

INTRODUCTION

- Vobra duo (MGC018) is an investigational B7 homolog 3 (B7-H3; CD276)–targeting ADC with a duocarmycin-based DNA-alkylating payload (**Figure 1**)
- B7-H3 is highly expressed in multiple solid tumors, including primary and metastatic mCRPC,[1,2] with limited expression in normal tissue[1,3]

Figure 1. B7-H3–Directed ADC Vobra Duo With Duocarmycin-Based Linker Payload[4]



IgG1, immunoglobulin G1; mAb, monoclonal antibody.

- Phase 1 testing of vobra duo (CP-MGC018-01/NCT03729596) demonstrated acceptable short-term safety at doses up to 4.0 mg/kg IV every 3 weeks (Q3W) in study participants with solid tumors[5]
- In the interim analysis of an expansion cohort of study participants with mCRPC who received vobra duo at 3.0 mg/kg Q3W on study CP-MGC018-01, adverse events (AE) resulted in discontinuation, dose reduction, or interruption of drug in 10%, 30%, and 55% of study participants, respectively, and the median number of doses received was 3.5 (range, 1.0-8.0)[6]
- The TAMARACK study was designed to test the hypothesis that lowering the starting dose of vobra duo while increasing the dosing interval may improve tolerability (by delaying onset, incidence, and severity of AEs), extend treatment duration (by reducing the need for dose modifications), and maintain or enhance the efficacy of vobra duo in study participants with mCRPC

METHODS

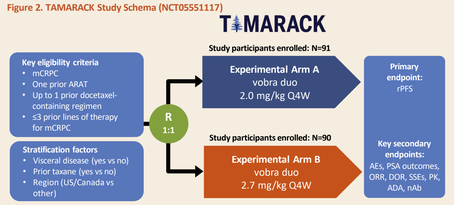
CP-MGC018-01 (Phase 1) Study Design

- The phase 1 study CP-MGC018-01 enrolled men with mCRPC who had progressed after 1 prior line of chemotherapy for metastatic disease and no more than 2 prior lines of antihormonal therapy
- Study participants were required to have a prostate-specific antigen (PSA) ≥2 ng/mL and documented progressive disease (PD) per Prostate Cancer Working Group 2 (PCWG2) criteria
- Study participants received vobra duo at a dose of 3.0 mg/kg Q3W until PD per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, AEs requiring discontinuation, physician decision, withdrawal of consent, or maximum allowed treatment duration (26 cycles or 2 years) was reached
- Tumor response and radiographic progression-free survival (rPFS) were assessed every 9 weeks by the investigator using RECIST v1.1 criteria and PCWG2 criteria, respectively. PSA was assessed Q3W using PCWG2 criteria
- For additional methods regarding the phase 1 study CP-MGC018-01, please refer to previous related publications[5,6]

TAMARACK (Phase 2) Study Design[7]

- TAMARACK is a randomized, open-label, global, phase 2 dose-selection[8] study assessing the efficacy, safety, and tolerability of vobra duo at 2 dose levels (2.0 mg/kg and 2.7 mg/kg IV Q4W) in study participants with mCRPC (**Figure 2**)

Figure 2. TAMARACK Study Schema (NCT05551117)



ADA, antidrug antibody; DOR, duration of response; nAb, neutralizing antibody; ORR, objective response rate; PK, pharmacokinetics; R, randomized; SSE, symptomatic skeletal event; US, United States.

- The study population included men with mCRPC previously treated with 1 prior ARAT (abiraterone, enzalutamide, or apalutamide) for prostate cancer in either the metastatic or nonmetastatic, castration-sensitive or castration-resistant setting
- Study participants were to receive vobra duo until PD per Prostate Cancer Working Group 3 (PCWG3), AEs requiring discontinuation, physician decision, withdrawal of consent, or maximum allowed treatment duration (26 cycles or 2 years) was reached. On July 23, 2024, after the data cutoff date for this presentation, vobra duo was discontinued in all remaining study participants on treatment (n=32) after review of the totality of data, including efficacy and emerging AEs associated with prolonged exposure and considering potential risk/benefit to participants. Most (n=27) of these remaining study participants had already received 8+ cycles of vobra duo. All study participants continue to be monitored for AEs, PD, and survival
- The primary endpoint was rPFS rate at 6 months as assessed by investigators using PCWG3 criteria
- Key secondary endpoints included: safety, proportion of patients with ≥50% decrease in PSA (PSA50 response), ORR, and DOR

TAMARACK Key Eligibility Criteria

- Adult study participants with histologically confirmed adenocarcinoma of the prostate with metastatic and castration-resistant disease
- Study participants with ≥1 metastatic lesion present on magnetic resonance imaging, computed tomography, or bone scan obtained ≤28 days before initiation of study treatment
- Tumor progression at study entry documented by PSA or imaging per PCWG3 criteria
- Received 1 prior ARAT and up to 1 prior docetaxel-containing regimen for metastatic or nonmetastatic, castration-sensitive or castration resistant prostate cancer. A second ARAT regimen or a second taxane regimen of <60 days used as bridging to lutetium Lu 177 vipivotide tetraxetan was permitted, but other prior chemotherapy for prostate cancer was not allowed except in the 11 study participants who enrolled under Protocol Amendment 1
- Having received >3 total prior lines of therapy for mCRPC was not allowed
- Eastern Cooperative Oncology Group performance status (ECOG PS) of ≤2 and acceptable laboratory values

TAMARACK Efficacy Assessment

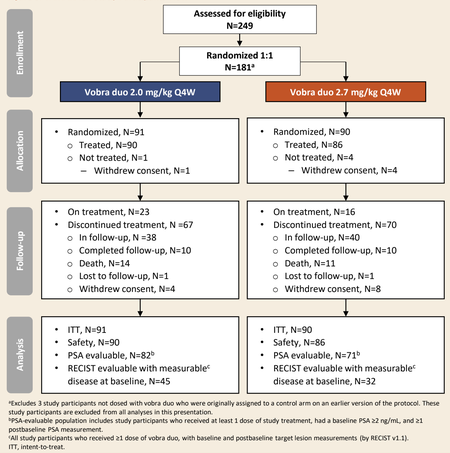
- Tumor response was evaluated by investigators approximately every 8 weeks for the first 24 weeks and every 12 weeks after that until PD, death, initiation of another anticancer therapy, withdrawal of consent, lost to follow-up, or end of study, whichever occurred first
- PSA was assessed at baseline and Q4W while on study treatment. During the follow-up period, PSA was assessed approximately every 12 weeks for up to 6 months from last dose of vobra duo until PD, death, initiation of another anticancer therapy, withdrawal of consent, lost to follow-up, or end of study, whichever occurred first

RESULTS

TAMARACK Study Participants

- Between June 9, 2023 and November 17, 2023, 181 study participants were enrolled and randomized to either vobra duo at 2.0 mg/kg Q4W (n=91) or 2.7 mg/kg Q4W (n=90; **Figure 3**)

Figure 3. TAMARACK Study Participants Flow



[a]Excludes 3 study participants not dosed with vobra duo who were originally assigned to a control arm on an earlier version of the protocol. These study participants are excluded from all analyses in this presentation.
[b]PSA-evaluable population includes study participants who received at least 1 dose of study treatment, had a baseline PSA ≥2 ng/mL, and ≥1 postbaseline PSA measurement.
[c]All study participants who received ≥1 dose of vobra duo, with baseline and postbaseline target lesion measurements (by RECIST v1.1).
ITT, intent-to-treat.

TAMARACK Baseline Characteristics

- Enrolled study participants had a median age of 70 years (range, 35-89) and 88 study participants (48.6%) had an ECOG PS of 1 or 2 (**Table 1**)
- Thirty (16.6%) study participants had visceral disease at baseline, with liver or lung disease in 25 (13.8%) study participants, 81 (44.8%) had measurable disease at baseline, and 97 (53.6%) had received prior taxane (**Table 1**)

Table 1. TAMARACK Demographics and Baseline Characteristics (ITT Population, N=181)[a]

Parameter	Vobra duo 2.0 mg/kg Q4W N=91	Vobra duo 2.7 mg/kg Q4W N=90
Median (range) age, years	71 (46-89)	69 (35-86)
ECOG PS, n (%)		
0	42 (46.2)	51 (56.7)
1	48 (52.7)	37 (41.1)
2	1 (1.1)	2 (2.2)
Disease status at first diagnosis, n (%)		
Local resectable	28 (30.8)	37 (41.1)
Locally advanced unresectable	12 (13.2)	9 (10.0)
Metastatic	51 (56.0)	44 (48.9)
Type of disease progression at study entry, n (%)		
Radiographic progression of measurable disease	43 (47.3)	31 (34.4)
Radiographic progression of bone disease (in >2 new bone lesions)	33 (36.3)	41 (45.6)
PSA progression only	24 (26.4)	25 (27.8)
PSA progression with any other type of progression	39 (42.9)	32 (35.6)
Study participants with visceral disease, n (%)	15 (16.5)	15 (16.7)
Study participants with prior taxane, n (%)	48 (52.7)	49 (54.4)
Study participants with prior PARP, n (%)	6 (6.6)	8 (8.9)
Number of prior ARAT, n (%)		
1	82 (90.1)	84 (93.3)
>1	9 (9.9)	6 (6.7)
Type of prior ARAT, n (%)		
Abiraterone	46 (50.5)	48 (53.3)
Enzalutamide	37 (40.7)	34 (37.8)
Apalutamide	12 (13.2)	11 (12.2)
Darolutamide	5 (5.5)	3 (3.3)
Sites of disease at baseline, n (%)		
Lymph node only	5 (5.5)	8 (8.9)
Bone only	31 (34.1)	38 (42.2)
Bone with lymph node	25 (27.5)	18 (20.0)
Liver	7 (7.7)	5 (5.6)
Lung	6 (6.6)	7 (7.8)
Other	17 (18.7)	14 (15.6)
Baseline PSA		
n	89	85
Mean (standard deviation), ng/mL	180.5 (542.60)	182.6 (433.06)
Median (range), ng/mL	26.4 (0.8-3447.0)	24.7 (0.2-2778.0)
PSA ≥2 ng/mL, n (%)	83 (91.2)	74 (82.2)

[a]All randomized study participants, including the study participants not treated.
PARP, poly (ADP-ribose) polymerase.

Disposition and Exposure

- At data cutoff (July 9, 2024), 176 of the 181 enrolled study participants on the TAMARACK study received vobra duo at either 2.0 mg/kg Q4W (n=90) or 2.7 mg/kg Q4W (n=86; **Table 2**)
- On the earlier CP-MGC018-01 study, 41 study participants with mCRPC enrolled in the expansion cohort received vobra duo at 3.0 mg/kg Q3W (**Table 2**)

Table 2. Treatment Exposure and Reason for Treatment Discontinuation in TAMARACK and CP-MGC018-01

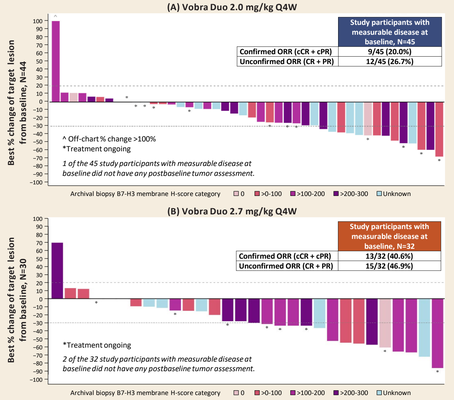
	TAMARACK vobra duo 2.0 mg/kg Q4W	TAMARACK vobra duo 2.7 mg/kg Q4W	CP-MGC018-01 vobra duo 3.0 mg/kg Q3W
Treated with any study treatment, n	90	86	41
Treatment discontinued, n (%)	67 (74.4)	70 (81.4)	41 (100)
Adverse event	22 (24.4)	31 (36.0)	15 (36.6)
Death	2 (2.2)	2 (2.3)	0
Physician decision	5 (5.6)	2 (2.3)	0
Progressive disease	28 (31.1)	28 (32.6)	24 (58.5)
Subject decision/withdrew consent	10 (11.1)	7 (8.1)	2 (4.9)
Treatment ongoing, n (%)	23 (25.6)	16 (18.6)	0
Mean (standard deviation) number of doses	6.1 (2.35)	5.5 (2.39)	5.0 (2.98)
Median (range) number of doses	6 (1-11)	6 (1-12)	4.0 (1.0-15.0)
Median (range), duration study treatment, months	6.4 (1.0-11.1)	6.7 (1.0-12.9)	4.2 (2.1-15.0)
Median (range) dose intensity,[a] %	92.6 (64.2-106.1)	81.7 (40.5-104.3)	66.4 (26.7-102.9)

[a]Total dose intensity is calculated as total dose administered / total planned dose × 100. Total planned dose = assigned dose at randomization * baseline weight * [(last dose date – first dose date) / 28 + 1] rounded to the nearest whole number.

Efficacy

- In the TAMARACK study, among RECIST response-evaluable study participants with measurable disease at baseline:
  - Confirmed ORR was 20.0% (9/45) and unconfirmed ORR was 26.7% (12/45) in the 2.0 mg/kg arm (**Figure 4A, Table 3**)
  - Confirmed ORR was 40.6% (13/32) and unconfirmed ORR was 46.9% (15/32) in the 2.7 mg/kg arm (**Figure 4B, Table 3**)
- In CP-MGC018-01 (3.0 mg/kg), among RECIST response-evaluable study participants with measurable disease at baseline, confirmed ORR was 8.3% (2/24) and unconfirmed ORR was 25.0% (6/24)
- Tumor responses do not appear to correlate with baseline B7-H3 expression based on archival tissue samples of mixed age

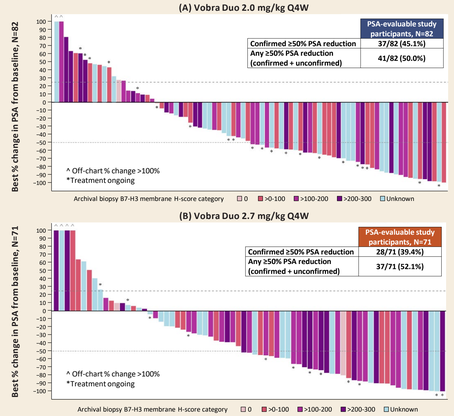
Figure 4. TAMARACK Best % Change in Target Lesions From Baseline per Investigator (RECIST Response-Evaluable Population With Measurable Disease, N=77)[a]



[a]All study participants who received ≥1 dose of vobra duo, with baseline and postbaseline target lesion measurements (by RECIST v1.1).
cCR, confirmed complete response; CR, complete response; cPR, confirmed partial response; PR, partial response.

- In the TAMARACK study, among PSA response-evaluable study participants:
  - Confirmed PSA50 response was 45.1% (37/82) and any PSA50 response was 50.0% (41/82) in the 2.0 mg/kg arm (**Figure 5A, Table 3**)
  - Confirmed PSA50 response was 39.4% (28/71) and any PSA50 response was 52.1% (37/71) in the 2.7 mg/kg arm (**Figure 5B, Table 3**)
- In CP-MGC018-01, all study participants in the expansion cohort were PSA-evaluable. Among these study participants, the confirmed PSA50 response rate was 43.9% (18/41) and any PSA50 response was 63.4% (26/41)
- PSA responses do not appear to correlate with baseline B7-H3 expression based on archival tissue samples of mixed age

Figure 5. TAMARACK Best % Change From Baseline in PSA (PSA Response-Evaluable Population, N=153)[a]



[a]All study participants who received ≥1 dose of vobra duo, with a baseline PSA ≥2 ng/mL and ≥1 postbaseline PSA measurement.

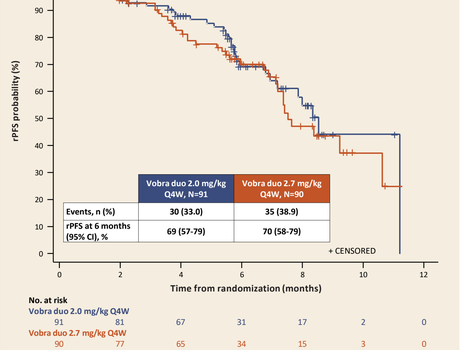
Table 3. TAMARACK Tumor and PSA Responses

	Vobra duo 2.0 mg/kg Q4W	Vobra duo 2.7 mg/kg Q4W
RECIST response-evaluable population with baseline measurable disease[a]	**N=45**	**N=32**
Best overall response (confirmed), n (%)		
CR	0	1 (3.1)
PR	9 (20.0)	12 (37.5)
SD	30 (66.7)	15 (46.9)
PD	5 (11.1)	2 (6.3)
NE	1 (2.2)	2 (6.3)
Confirmed ORR (CR + PR), n (%)	9 (20.0)	13 (40.6)
Confirmed + unconfirmed ORR, n (%)	12 (26.7)	15 (46.9)
Median (range) DOR of confirmed RECIST responders, months [n]	4.9 (1.94-6.47) [9]	NE (1.54-9.46) [13]
PSA response-evaluable population[b]	**N=82**	**N=71**
PSA50 response (confirmed), n (%)	37 (45.1)	28 (39.4)
PSA50 response (confirmed + unconfirmed), n (%)	41 (50.0)	37 (52.1)
Median (range) DOR of confirmed PSA50 responders, months [n]	NE (0.95-9.23) [37]	NE (0.95-9.49) [28]

[a]All study participants who received ≥1 dose of vobra duo, with baseline and postbaseline target lesion measurements (by RECIST v1.1).
[b]All study participants who received ≥1 dose of vobra duo, with a baseline PSA ≥2 ng/mL and ≥1 postbaseline PSA measurement.
NE, not evaluable; SD, stable disease.

- In the TAMARACK study, the protocol-specified primary endpoint, landmark 6-month rPFS rate, in the ITT population was 69% (95% CI, 57-79) for the 2.0 mg/kg arm and 70% (95% CI, 58-79) for the 2.7 mg/kg arm (**Figure 6**). Although immature, with only 65 (35.9%) rPFS events as of the data cutoff date, median rPFS is currently 8.5 months (95% CI, 7.2-11.2) on the 2.0 mg/kg arm and 7.5 months (95% CI, 7.2-10.6) on the 2.7 mg/kg arm
- In CP-MGC018-01, median rPFS on the mCRPC expansion cohort was 5.5 months (95% CI, 2.9-8.3)

Figure 6. TAMARACK rPFS per Investigator by PCWG3 (ITT Population, N=181)



Safety

- An overall summary of treatment-emergent AEs (TEAE) on the TAMARACK and the CP-MGC018-01 studies is presented in **Table 4**

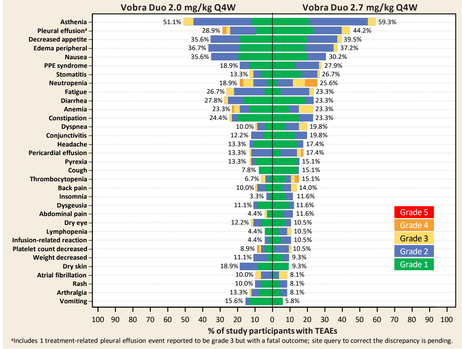
Table 4. Overall Summary of TEAEs on TAMARACK and CP-MGC018-01

AEs, n (%)	Vobra duo 2.0 mg/kg Q4W N=90	Vobra duo 2.7 mg/kg Q4W N=86	CP-MGC018-01 3.0 mg/kg Q3W N=41
Any TEAE	89 (98.9)	86 (100)	41 (100)
Treatment-related AEs[a]	87 (96.7)	84 (97.7)	41 (100)
Any grade ≥3 TEAE	59 (65.6)	54 (62.8)	33 (80.5)
Grade ≥3 treatment-related AE[a]	42 (46.7)	45 (52.3)	32 (78.0)
Any SAE	34 (37.8)	38 (44.2)	23 (56.1)
Treatment-related SAEs[a]	23 (25.6)	24 (27.9)	19 (46.3)
Fatal treatment-related AEs	5 (5.6)	3 (3.5)	2 (4.9)
TEAEs resulting in vobra duo discontinuation	23 (25.6)	33 (38.4)	15 (36.6)
TEAEs resulting in vobra duo dose reductions	45 (50.0)	47 (54.7)	28 (68.3)
TEAEs resulting in vobra duo interruption	46 (51.1)	51 (59.3)	28 (68.3)

[a]Includes events with causality assessments of "possible," "probable," or "definite," per investigator.
SAE, serious adverse event.

- In TAMARACK, the most common (occurring in ≥20% of study participants on the 2.0 mg/kg vobra duo or the 2.7 mg/kg vobra duo arm, respectively) all-grade TEAEs were asthenia (51.1% vs 59.3%), edema peripheral (36.7% vs 37.2%), decreased appetite (35.6% vs 39.5%), nausea (35.6% vs 30.2%), pleural effusion (28.9% vs 44.2%), diarrhea (27.8% vs 23.3%), fatigue (26.7% vs 23.3%), constipation (24.4% vs 23.3%), anemia (23.3% vs 23.3%), palmar-plantar erythrodysesthesia (PPE) syndrome (18.9% vs 27.9%), neutropenia (18.9% vs 25.6%), and stomatitis (13.3% vs 26.7%; **Figure 7**)
- Fatal treatment-related AEs on TAMARACK were pneumonitis (n=3), cardiac failure, stress cardiomyopathy, ventricular fibrillation, pleural effusion, and gastrointestinal hemorrhage (n=1 each). Fatal treatment-related AEs on CP-MGC018-01 were cardiac arrest and disseminated intravascular coagulation (n=1 each).

Figure 7. TEAEs Reported in ≥10% of Study Participants in Either Arm of TAMARACK (Safety Population, N=176)



*Includes 1 treatment-related pleural effusion event reported to be grade 3 but with a fatal outcome; site query to correct the discrepancy is pending.

- Fewer TEAEs of pleural effusion, pericardial effusion, and PPE syndrome occurred in the 2.0 mg/kg arm versus the 2.7 mg/kg arm, and generally most of these AEs were of grade 1/2 (**Figure 8**)
- TEAEs of pleural effusion, pericardial effusion, and PPE syndrome occurred in 36.4%, 15.3%, and 23.3%, respectively, of the participants on TAMARACK and 48.8%, 17.1%, and 46.3%, respectively, of the participants on the earlier phase 1 study despite the longer median duration of study treatment on TAMARACK (**Figure 8 and Table 2**)

Figure 8. Select TEAEs by Grade and Dose in TAMARACK (Safety Population, N=176) and in CP-MGC018-01 (Safety Population, N=41)

*Includes 1 treatment-related pleural effusion event reported to be grade 3 but with a fatal outcome; site query to correct the discrepancy is pending.

Outcomes by Prior Taxane Use in TAMARACK

- Confirmed ORR was 26.7% (12/45) in participants who did not receive prior taxane and 17.5% (11/63) in those who received prior taxane, regardless of dose
- Confirmed PSA50 response rate was 47.6% (30/63) in participants who did not receive prior taxane and 38.9% (35/90) in those who received prior taxane, regardless of dose
- The 6-month rPFS rate ranged from 66% to 82% in participants who did not receive prior taxane and ranged from 60% to 73% in those who received prior taxane
- Rates of treatment-related AEs (all grades and grade ≥3) were 97.3% and 50.7%, respectively, in participants who did not receive prior taxane and, 97.0% and 48.5%, respectively, in participants who received prior taxane; rates of treatment-related SAEs were 28.0% in participants who did not receive prior taxane and 25.7% in participants who received prior taxane
- Rates of discontinuation, dose reductions, and dose interruptions due to TEAEs were 34.7%, 62.7%, and 70.7%, respectively, in participants who did not receive prior taxane and 29.7%, 44.6%, and 43.6%, respectively in participants who received prior taxane
- The rate of pleural and pericardial effusions was 34.7% (26/75) and 18.7% (14/75), respectively, in participants who did not receive prior taxane; rates of pleural and pericardial effusions were 37.6% (38/101) and 12.9% (13/101), respectively, in those who received prior taxane

CONCLUSIONS

- Vobra duo yields antitumor activity in mCRPC as demonstrated by ORR, PSA response rate, and 6-month rPFS rate
- Treatment with 2.7 mg/kg Q4W yielded a higher ORR than 2.0 mg/kg Q4W; with PSA responses similar between the two arms
- Six-month landmark rPFS rates for 2.7 mg/kg Q4W and 2.0 mg/kg Q4W are comparable
- Events of neutropenia, anemia, thrombocytopenia, pleural effusion, and PPE syndrome improved with reduction of the starting dose and dosing frequency
- Adverse events associated with prolonged exposure to vobra duo, including edema, pleural effusions, and pericardial effusions, the latter two of which were less frequent with a 2.0 mg/kg starting dose, could possibly be mitigated by a longer dosing interval (eg, every 6 weeks) or by use of a loading dose strategy
- As of the data cutoff date, median rPFS is considered immature and subject to potential change, given that only 35.9% of participants have had rPFS events. Maturation of rPFS is awaited

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DISCLOSURES

Professor Johann de Bono has served on advisory boards and received fees from companies, including Amgen, AstraZeneca, Astellas, Bayer, BioXcel Therapeutics, Daiichi Sankyo, Genentech/Roche, GlaxoSmithKline, Harpoon Therapeutics, ImCheck Therapeutics, Janssen, Merck Serono, Merck Sharp & Dohme (MSD), Pfizer, and Sanofi Aventis. Professor Johann de Bono is an employee of The Institute of Cancer Research (ICR), which has received funding or other support for his research work from AstraZeneca, Astellas, Bayer, CellCentric, Daiichi Sankyo, Genentech, Genmab, GlaxoSmithKline, Janssen, Merck Serono, MSD, Menarini Silicon Biosystems, Orion Pharma, Sanofi Aventis, Sierra Oncology, Taiho Pharmaceutical, Pfizer, and Vertex Pharmaceuticals. The ICR has a commercial interest in abiraterone and PARP inhibition in DNA repair-defective cancers and PI3K/AKT pathway inhibitors (no personal income). Professor Johann de Bono was named as an inventor, with no financial interest for patent 8,822,438, submitted by Janssen that covers the use of abiraterone acetate with corticosteroids. He has been the chief investigator / principal investigator of many industry-sponsored clinical trials. Professor Johann de Bono is a National Institute for Health Research (NIHR) Senior Investigator. The views expressed in this article are those of the author(s) and not necessarily those of the National Health Service, the NIHR, or the Department of Health.

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