Real-World Comparison of Prostate-Specific Antigen Response in Patients with Metastatic Castration-Sensitive Prostate Cancer Treated with Apalutamide or Enzalutamide (PROMPT-1)

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Presented at American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU); January 25-27, 2024; San Francisco, CA and online.

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KEY TAKEAWAY

In this real-world study of patients with mCSPC, significantly more patients treated with apalutamide attained an early and deep PSA90 response when compared to patients treated with enzalutamide

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CONCLUSIONS

- In patients with mCSPC, a higher proportion of patients treated with apalutamide attained a PSA90 response than those treated with enzalutamide
- PSA90 response was attained earlier in patients treated with apalutamide than those treated with enzalutamide
- These findings confirm results from a prior study that reported higher rates of PSA90 for apalutamide initiators than enzalutamide initiators who were treated through community-based urology practices with IOD[6]
- The proportions of patients with PSA90 response by 12 months following initiation of apalutamide in this real-world study are consistent with those observed in patients with mCSPC enrolled in the phase III TITAN study[11]
- The clinical implications of these observations warrant further consideration given existing evidence on the association between attainment of rapid and deep PSA response with survival-related endpoints in patients treated with these medications[1,2]

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BACKGROUND

- Deep prostate-specific antigen (PSA) response (≥90% reduction in PSA [PSA90]) has been associated with radiographic progression-free survival (rPFS) and overall survival (OS) in patients with metastatic castration-sensitive prostate cancer (mCSPC)[1,2]
- Apalutamide, an androgen receptor signaling inhibitor (ARSI), combined with androgen deprivation therapy (ADT) resulted in significant improvements in rPFS and OS versus placebo plus ADT in the TITAN trial[3,4]
- Similarly, enzalutamide combined with ADT significantly improved rPFS and OS versus placebo plus ADT in the ARCHES trial[5]
- A prior real-world study in community-based urology practices in the United States (US) found that apalutamide was associated with 56% higher PSA90 response rates than enzalutamide among patients with mCSPC at 6-months post-treatment initiation, as verified by medication receipt with in-office dispensing (IOD)[6]
- This study aimed to replicate the prior analysis comparing real-world PSA response in an enhanced cohort of patients with mCSPC by verifying apalutamide or enzalutamide medication receipt using linked clinical and administrative claims data

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OBJECTIVES

- To compare the proportion of patients with a PSA reduction ≥90% from baseline (PSA90 response) by 6 months for patients with mCSPC who newly initiated apalutamide versus enzalutamide

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METHODS (1 of 5)

Data sources

- Clinical data from Precision Point Specialty (PPS) Analytics collected as part of routine clinical care from community-based urology practices in the US linked with administrative claims data from the Komodo Research Database (study period: 16 December 2018 - 30 September 2022)
- Data are de-identified and Health Insurance Portability and Accountability Act (HIPAA) compliant

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METHODS (2 of 5)

Study design

- A retrospective longitudinal propensity score-weighted cohort study of patients with mCSPC initiated on apalutamide or enzalutamide was conducted
- Patients were assigned to mutually exclusive treatment cohorts based on the first dispensation or paid pharmacy claim for apalutamide or enzalutamide
- Index date was defined as the first dispensation or paid pharmacy claim for apalutamide or enzalutamide after 16 December 2019 (the US Food and Drug Administration approval date for enzalutamide[7] which followed apalutamide approval on 17 September 2019[8])
- Baseline patient characteristics were evaluated in the 12 months preceding the index date
- The observation period spanned from the index date to the earliest of index treatment discontinuation (using a 90-day treatment gap to define discontinuation), initiation of a non-index ARSI (i.e., apalutamide, abiraterone acetate, darolutamide, or enzalutamide) or a radiopharmaceutical agent, end of insurance or clinical activity (including death), or end of data availability (30 September 2022)

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Patient selection criteria

FIGURE 1: Patient Identification Flowchart

- Concurrent use of ADT was not required for patients to be included in either the apalutamide or enzalutamide cohort

≥1 paid claim or filled dispensation for any ARSI on or after 16 December 2019
(first paid claim or dispensation defined as the index date)[a]
N=17,739

Apalutamide as first paid claim or filled dispensation	Enzalutamide as first paid claim or filled dispensation
N=2,818 (15.9%)	**N=6,072 (34.2%)**

Criterion	Apalutamide	Enzalutamide
Only a paid claim or filled dispensation for a single ARSI on or prior to the index date[b]	**N=2,591 (91.9%)**	**N=5,217 (85.9%)**
No filled dispensation or prescription for any ARSI other than the index ARSI, observed from beginning of data to index date (inclusive)	**N=2,409 (93.0%)**	**N=4,762 (91.3%)**
mCSPC status on index date	**N=1,591 (66.0%)**	**N=2,059 (43.2%)**
≥1 year of clinical activity prior to index date[c]	**N=1,136 (71.4%)**	**N=1,369 (66.5%)**
≥1 PSA measurement in the 13-week period prior to and including the index date	**N=862 (75.9%)**	**N=871 (63.6%)**
≥18 years of age on index date	**N=862 (100.0%)**	**N=871 (100.0%)**
No use of radiopharmaceutical therapy any time prior to or on index date	**N=862 (100.0%)**	**N=871 (100.0%)**
	Apalutamide cohort **N=862**	Enzalutamide cohort **N=871**

ARSI: androgen receptor signaling inhibitor; mCSPC: metastatic castration-sensitive prostate cancer; PSA: prostate-specific antigen.

Notes:

a. The Food and Drug Administration (FDA) approved enzalutamide as treatment for mCSPC on 16 December 2019. b. To ensure that patients were assigned to a cohort based on the first claim for an ARSI, all claims were considered to exclude patients with other claims prior to index date. c. Clinical activity was defined as the period from the first to last record in the Precision Point Specialty (PPS) electronic medical records (EMR) database. Patients with no observation period after the index date were excluded.

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METHODS (4 of 5)

Study outcomes

- The primary outcome was the proportion of patients who achieved at least a 90% reduction in PSA (PSA90) from the most recent baseline value by 6 months post-index
- The exploratory outcome was the time to PSA90 response from the date of index treatment initiation

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Statistical analysis

- Inverse probability of treatment weighting (IPTW), based on the propensity score (PS), was used to account for differences in baseline characteristics between the apalutamide and enzalutamide cohorts[9]
- The PS was obtained from a logistic regression model where index treatment was the dependent variable and with the following baseline characteristics as independent variables: age, race, geographic region, payer type, index year, time between metastasis and index date, time between first prostate cancer (PC) diagnosis and index date, *de novo* PC, prior ADT use, first-generation antiandrogen use, chemotherapy use, metastasis location, most recent PSA level, most recent testosterone level, and most recent Gleason score
- Balancing of baseline characteristics between treatment cohorts after weighting was confirmed by standardized differences <10% which indicates balance[10]
- Weighted Kaplan-Meier analysis was used to assess the proportion of patients achieving PSA90 by 3-, 6-, 9-, and 12-months post-index, as well as the median time to PSA90
- Weighted Cox proportional hazards models were used to evaluate the causal relationship between index treatment and the likelihood of achieving PSA90
- Results from this analysis were updated after the abstract submission to consider patient date of death information from both data sources when censoring the observation period. This update did not result in changes in the interpretation of the study findings

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Baseline characteristics

TABLE 1: Baseline Characteristics

- Overall, 862 patients with mCSPC who initiated apalutamide and 871 patients with mCSPC who initiated enzalutamide were identified (**Figure 1**)
- Baseline patient characteristics were generally well-balanced between the weighted cohorts, with standardized differences <10% (**Table 1**)

	Non-weighted Population			IPTW Population[a]		
	Apalutamide N=862	Enzalutamide N=871	Standardized Difference[b]	Apalutamide N=862	Enzalutamide N=871	Standardized Difference[b]
Age, mean ± SD [median]	**73.9 ± 8.4 [74.0]**	**74.1 ± 8.8 [74.0]**	**2.3**	**74.1 ± 8.4 [74.0]**	**74.1 ± 8.9 [74.0]**	**0.2**
Age group, n (%)						
≤60	51 (5.9)	53 (6.1)	0.7	50 (5.8)	56 (6.4)	2.7
61-70	245 (28.4)	248 (28.5)	0.1	240 (27.9)	247 (28.3)	1.0
71-80	377 (43.7)	360 (41.3)	4.9	380 (44.1)	359 (41.2)	5.8
≥81	189 (21.9)	210 (24.1)	5.2	192 (22.3)	210 (24.1)	4.3
Race, n (%)						
White	628 (72.9)	574 (65.9)	15.1	606 (70.4)	604 (69.4)	2.2
Black	156 (18.1)	179 (20.6)	6.2	160 (18.5)	164 (18.8)	0.8
Asian	4 (0.5)	7 (0.8)	4.3	4 (0.5)	7 (0.8)	4.1
Other/Unknown	74 (8.6)	111 (12.7)	13.5	92 (10.6)	96 (11.0)	1.2
Geographic region, n (%)						
South	473 (54.9)	405 (46.5)	16.8	442 (51.3)	438 (50.3)	2.1
Midwest	202 (23.4)	269 (30.9)	16.8	226 (26.2)	237 (27.2)	2.2
Northeast	102 (11.8)	113 (13.0)	3.5	109 (12.7)	108 (12.4)	1.0
West	85 (9.9)	79 (9.1)	2.7	84 (9.8)	84 (9.7)	0.3
Unknown	0 (0.0)	5 (0.6)	10.8	0 (0.0)	4 (0.5)	10.1
Payer type, n (%)						
Medicare	629 (73.0)	644 (73.9)	2.2	633 (73.5)	641 (73.6)	0.2
Commercial	154 (17.9)	160 (18.4)	1.3	156 (18.1)	158 (18.2)	0.3
Medicaid	25 (2.9)	16 (1.8)	7.0	20 (2.3)	19 (2.2)	1.1
Unknown	54 (6.3)	51 (5.9)	1.7	53 (6.1)	53 (6.1)	0.1
Year of treatment initiation (index date), n (%)						
2019-2020	247 (28.7)	296 (34.0)	11.5	263 (30.5)	272 (31.2)	1.5
2021	324 (37.6)	353 (40.5)	6.0	338 (39.2)	344 (39.5)	0.5
2022	291 (33.8)	222 (25.5)	18.2	260 (30.2)	255 (29.3)	2.0
Time between metastasis and treatment initiation, months, mean ± SD [median]	**9.6 ± 18.1 [2.4]**	**12.0 ± 18.6 [3.4]**	**13.2**	**10.6 ± 20.0 [2.4]**	**11.0 ± 17.3 [3.2]**	**2.0**
Time between PC diagnosis and treatment initiation, months, mean ± SD [median]	**52.1 ± 49.2 [44.0]**	**47.1 ± 45.5 [36.0]**	**10.7**	**49.0 ± 47.4 [41.0]**	**48.5 ± 46.4 [37.5]**	**1.2**
Metastasis type, n (%)						
Bone	577 (66.9)	605 (69.5)	5.4	590 (68.4)	598 (68.6)	0.4
Nodal	442 (51.3)	391 (44.9)	12.8	419 (48.6)	417 (47.9)	1.4
Visceral	152 (17.6)	177 (20.3)	6.9	156 (18.1)	161 (18.5)	1.2
De novo Pct., n (%)	**332 (38.5)**	**383 (44.0)**	**11.1**	**356 (41.3)**	**365 (42.0)**	**1.3**
Prior use of ADT[e], n (%)	**760 (88.2)**	**738 (84.7)**	**10.1**	**748 (86.8)**	**753 (86.5)**	**1.0**
Cumulative duration of prior ADT use, months, mean ± SD [median]	9.5 ± 13.0 [4.5]	10.7 ± 12.9 [6.0]	9.0	9.8 ± 13.6 [4.5]	10.4 ± 12.6 [6.0]	4.2
Prior use of first generation ARI[f], n (%)	**119 (13.8)**	**199 (22.8)**	**23.5**	**151 (17.5)**	**161 (18.5)**	**2.6**
Baseline PSA level[g], ng/mL, mean ± SD [median]	**20.9 ± 50.9 [3.3]**	**25.9 ± 59.9 [3.3]**	**9.0**	**22.7 ± 55.2 [3.3]**	**23.3 ± 55.8 [3.0]**	**1.1**
Baseline testosterone tests[h], n (%)	**572 (62.2)**	**374 (58.7)**	**7.1**	**556 (60.4)**	**393 (61.7)**	**2.7**
Testosterone <50 ng/dL[i]	359 (66.1)	367 (76.3)	22.6	713 (82.7)	728 (83.6)	2.5
Baseline Gleason score[j], n (%)						
≤6	71 (8.2)	61 (7.0)	4.7	68 (7.9)	63 (7.2)	2.7
7	228 (26.5)	165 (18.9)	18.0	208 (24.2)	184 (21.1)	7.4
8	111 (12.9)	132 (15.2)	6.6	112 (13.0)	135 (15.5)	7.2
9	174 (20.2)	155 (17.8)	6.1	166 (19.2)	163 (18.8)	1.2
10	21 (2.4)	29 (3.3)	5.3	25 (2.9)	25 (2.8)	0.6
Unknown	257 (29.8)	284 (44.6)	16.9	282 (32.8)	302 (34.6)	4.0

ADT: androgen deprivation therapy; ARI: androgen receptor inhibitor; IPTW: inverse probability of treatment weighting; PC: prostate cancer; PSA: prostate-specific antigen; SD: standard deviation.

Notes:

a. Propensity scores were generated using probability estimates from a logistic regression models using the following predictors: age (continuous), race, geographic region, payer, year of index date, time between metastasis and index date (continuous), time between first observed PC diagnosis and index date (continuous), *de novo* PC, previous ADT use, first-generation antiandrogen use, chemotherapy use, types of metastases (bone, nodal, visceral), most recent PSA level (continuous), baseline testosterone level (categorized as <50 ng/dL or ≥50 ng/dL; patients without a testosterone measurement were grouped into the <50 ng/dL category), and most Gleason score (categorized as ≤6, 7, 8, 9, 10 and missing). Each patient was attributed an inverse-probability of treatment weight that was defined as follows: 1/(propensity score) for the apalutamide cohort and 1/(1-propensity score) for the enzalutamide cohort). Normalized inverse-probability of treatment weights were truncated at the 95th percentiles. b. Standardized differences <10% indicate that the variable was balanced between the apalutamide and enzalutamide cohorts. c. Types of metastases were defined at any time prior to (and including) the index date. Types of metastases were not mutually exclusive. d. De novo PC was defined as ≤180 days between first observed PC diagnosis and date of metastasis. e. Prior use of ADT medication was defined as any ADT administration at any time prior to (and excluding) the index date. f. Prior use of first-generation ARI was defined as any prescription for bicalutamide, nilutamide, or flutamide, at any time prior to (and excluding) the index date. g. Baseline PSA was evaluated as the most recent value from 13 weeks pre-index up to, and including, the index date. h. Testosterone testing was evaluated during the 12-month baseline period and included the index date, with the most recent value reported. i. Patients' mCSPC status was evaluated using their records and baseline testosterone may not be synchronous with mCSPC designation. j. Gleason score was evaluated during the 12-month baseline period and included the index date, with the most recent value reported.

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PSA-related measurements

TABLE 2: Follow-Up PSA Testing

- PSA testing occurred more frequency among patients in the apalutamide cohort than the enzalutamide cohort (**Table 2**)
  - By 6 months post-index, 81.4% of apalutamide patients and 77.5% of enzalutamide patients had a post-index PSA measurement

	Non-weighted Population		IPTW Population[a]	
	Apalutamide N=862	Enzalutamide N=871	Apalutamide N=862	Enzalutamide N=871
Patients with ≥1 PSA test, n (%)	**720 (83.5)**	**677 (77.7)**	**717 (83.2)**	**683 (78.4)**
Within 3 months of observation	637 (73.9)	564 (64.8)	632 (73.3)	575 (66.0)
Within 6 months of observation	708 (82.1)	668 (76.7)	702 (81.4)	675 (77.5)
Number of follow-up PSA tests per year, mean ± SD [median]	**4.2 ± 3.3 [3.8]**	**3.7 ± 3.3 [3.5]**	**4.1 ± 3.2 [3.8]**	**3.8 ± 3.4 [3.6]**
Patients with PSA test on average every 3 months, n (%)	406 (47.1)	352 (40.4)	394 (45.7)	366 (42.1)
Patients with PSA test on average every 6 months, n (%)	677 (78.5)	629 (72.2)	670 (77.7)	638 (73.3)

ADT: androgen deprivation therapy; IPTW: inverse-probability of treatment weighting; PC: prostate cancer; PSA: prostate-specific antigen; SD: standard deviation.
Note:
a. Propensity scores were generated using probability estimates from a logistic regression models using the following predictors: age (continuous), race, geographic region, payer, year of index date, time between metastasis and index date (continuous), time between first observed PC diagnosis and index date (continuous), *de novo* PC, previous ADT use, first-generation antiandrogen use, chemotherapy use, types of metastases (bone, nodal, visceral), most recent PSA level (continuous), baseline testosterone level (categorized as <50 ng/dL or ≥50 ng/dL; patients without a testosterone measurement were grouped into the <50 ng/dL category), and most Gleason score (categorized as ≤6, 7, 8, 9, 10 and missing). Each patient was attributed an inverse-probability of treatment weight that was defined as follows: 1/(propensity score) for the apalutamide cohort and 1/(1-propensity score) for the enzalutamide cohort). Normalized inverse-probability of treatment weights were truncated at the 95th percentiles.

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Benjamin H. Lowentritt, Shawn Du, Dominic Pilon, Ibrahim Khilfeh, Erik Muser, Carmine Rossi, Frederic Kinkead, Lilian Diaz, Jill Korsiak, Lorie Ellis, Patrick Lefebvre, Gordon Brown

RESULTS (3 of 4)

PSA outcomes

- By 6 months post-index, apalutamide patients were 21% more likely to achieve a PSA90 response compared with similar patients initiated on enzalutamide (hazard ratio=1.21, 95% confidence interval [CI]: 1.05, 1.40; p=0.008; **Figure 2**)
- The same trend was observed over the entire observation period (p=0.008)
- PSA90 response was attained earlier in patients treated with apalutamide than for those treated with enzalutamide
  - The median time to PSA90 was 3.7 months for apalutamide and was 5.1 months for enzalutamide

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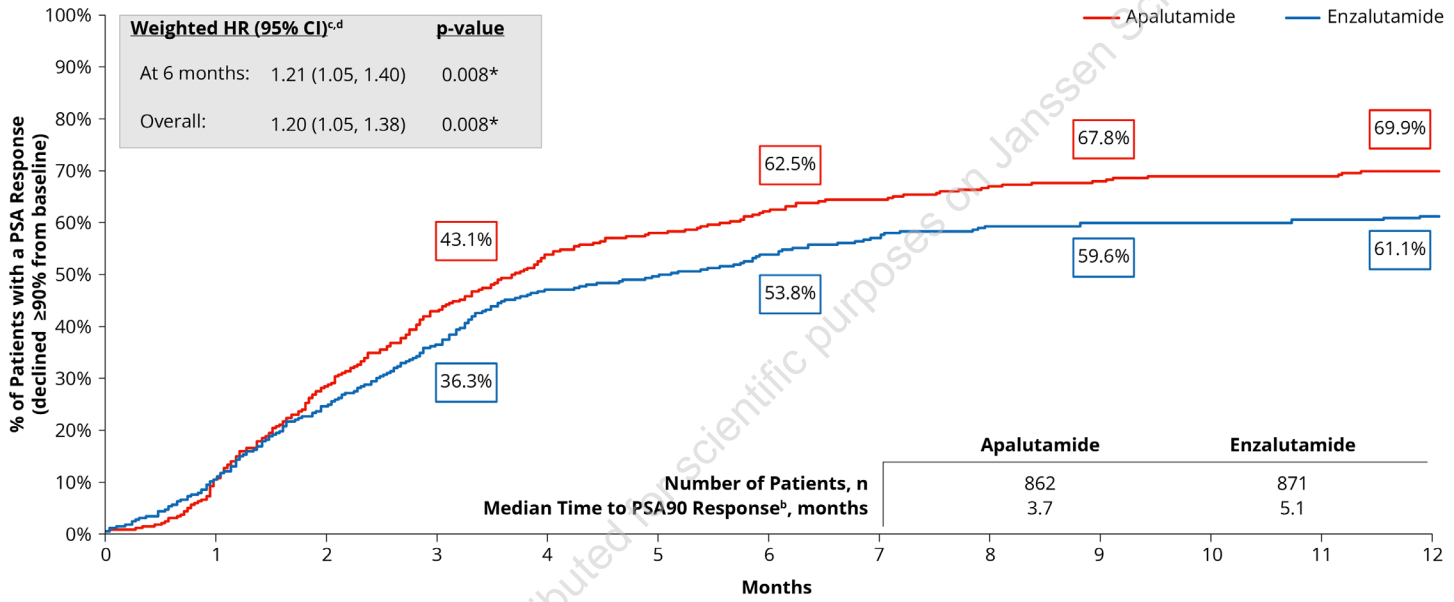
FIGURE 2: Comparison of Time to PSA90 Response Among Patients with mCSPC[a,b]



ADT: androgen deprivation therapy; CI: confidence interval; HR: hazard ratio; mCSPC: metastatic castration-sensitive prostate cancer; PC: prostate cancer; PSA: prostate-specific antigen.
*Significant at the 5% level.
Notes:
a. Results from this analysis were updated after the abstract submission. In the abstract, we had reported a weighted hazard ratio at 6 months of 1.23 (95% CI: 1.06, 1.42; p<0.001). This update did not result in changes in the interpretation of the study findings. b. PSA90 response was defined as the first decline for a follow-up PSA value of 90% or more relative to the most recent baseline PSA value observed within 13 weeks up to and including the index date. c. Propensity scores were generated using probability estimates from a logistic regression models using the following predictors: age (continuous), race, geographic region, payer, year of index date, time between metastasis and index date (continuous), time between first observed PC diagnosis and index date (continuous), *de novo* PC, previous ADT use, first-generation antiandrogen use, chemotherapy use, types of metastases (bone, nodal, visceral), most recent PSA level (continuous), baseline testosterone level (categorized as <50 ng/dL or ≥50 ng/dL; patients without a testosterone measurement were grouped into the <50 ng/dL category), and most Gleason score (categorized as ≤6, 7, 8, 9, 10 and missing). Each patient was attributed an inverse-probability of treatment weight that was defined as follows: 1/(propensity score) for the apalutamide cohort and 1/(1-propensity score) for the abiraterone acetate cohort). Normalized inverse-probability of treatment weights were truncated at the 95th percentiles. d. A hazard ratio >1 indicates that the apalutamide cohort had a higher rate of PSA response ≥90% compared to the enzalutamide cohort.

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LIMITATIONS

- Miscoding or misclassification in the clinical record or through the administrative claims may introduce selection and information biases despite efforts to match the study populations
- While robust methodology was applied to this analysis, this study did not address whether these findings represent a clinically meaningful difference or whether they translate into differences in longer-term outcomes (e.g., overall survival)
- The database represents the community urology perspective and may not be representative of the entire population of patients with mCSPC in the US, which may limit the generalizability of the study in certain settings

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DISCLOSURES:

B. Lowentritt is an employee of Chesapeake Urology Associates and has received consulting fees from Janssen Pharmaceuticals. S. Du, I. Khilfeh, and L. Ellis are employees of Janssen Pharmaceuticals and stockholders of Johnson & Johnson. D. Pilon, C. Rossi, F. Kinkead, L. Diaz, J. Korsiak, and P. Lefebvre are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to Janssen Pharmaceuticals. E. Muser was an employee of Janssen Pharmaceuticals at the time the study was conducted. G. Brown is an is an employee of New Jersey Urology and has received consulting fees from Janssen Pharmaceuticals.

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