

# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1\*</sup> Amitabha Bhaumik,<sup>2\*</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

<sup>1</sup>Johnson & Johnson, Spring House, PA, USA; <sup>2</sup>Johnson & Johnson, Raritan, NJ, USA; <sup>3</sup>Clinical Research Innovation, University of Utah Huntsman Cancer Institute, Salt Lake City, UT, USA; <sup>4</sup>Johnson & Johnson, Los Angeles, CA, USA; <sup>5</sup>Medical Oncology, Vancouver Prostate Centre, University of British Columbia, Vancouver, British Columbia, Canada; <sup>6</sup>Division of Hematology/Oncology, Department of Medicine, University of California, San Francisco, CA, USA; <sup>7</sup>Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco, CA, USA

*\*Contributed equally as the co-lead authors*

Presented by Dr Ruchi Chaudhary at the 2025 ASCO-GU Symposium; February 13-15, 2025; San Francisco, CA, USA



Click anywhere to view this interactive poster

<https://www.congresshub.com/Oncology/GU2025/Apalutamide/Chaudhary>



Copies of this presentation obtained through Quick Response (QR) Codes are for personal use only and may not be reproduced without permission from ASCO® or the author of this presentation.



# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## KEY TAKEAWAYS

-  Patients with radiographic progression without PSA progression (R-PD) are not uncommon in advanced prostate cancer
-  Poor prognosis of R-PD patients highlights the importance of monitoring them using imaging and warrants evaluation of new therapeutic approaches for them

PSA, prostate-specific antigen; R-PD, radiographic progression without prior or concurrent PSA progression.



## NAVIGATION



### KEY TAKEAWAY

### CONCLUSIONS

### INTRODUCTION

### METHODS

### Assessments & Analysis

### RESULTS

### Clinical Characteristics & Sites of Progression

### Time to Radiographic Progression

### Biomarker Analysis

### Overall Survival

### Supplementary Table 1

### APPENDIX

# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## CONCLUSIONS

- ✓ Approximately 10-12% of patients with advanced prostate cancer were R-PD in two randomized phase 3 trials of apalutamide-based regimes, with about equal proportion in each arm
- ✓ The addition of apalutamide to ADT prolonged the time to radiographic progression in R-PD patients
- ✓ Transcriptomic analysis of primary tumor from a subset of metastatic castration-sensitive patients showed both radiographic- and PSA progression-first patients at equally high risk
- ✓ R-PD patients had shorter overall survival compared with patients who had prior or concurrent PSA progression or no progression on the trial
- ✓ Our findings underscore the importance of monitoring advanced prostate cancer patients using imaging, independent of PSA dynamics
- ✓

ADT, androgen deprivation therapy; PSA, prostate-specific antigen; R-PD, radiographic progression without prior or concurrent PSA progression.



## NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX

# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## INTRODUCTION

- ARPIs are frequently combined with ADT to treat patients with CSPC or CRPC
- In the TITAN and SPARTAN studies, apalutamide (APA) added to continuous ADT improved
  - Radiographic progression-free survival, a co-primary endpoint of TITAN<sup>1</sup>
  - Metastasis-free survival, the primary endpoint of SPARTAN<sup>2</sup>
  - Overall survival and other long-term outcomes, despite crossover from placebo to APA after the studies were unblinded<sup>3,4</sup>
- Radiographic progression in the absence of prior or concurrent PSA progression serves as a critical biomarker for identifying patients at risk of poor clinical outcomes<sup>5</sup>
- **Here, we characterize patients who experienced R-PD and compare them with patients who experienced PSA-PD while undergoing treatment with ADT or ARPI + ADT**

1. Chi KN, et al. *N Engl J Med.* 2019; 381:13-24; 2. Smith MR, et al. *N Engl J Med.* 2018; 378:1408-18; 3. Chi KN, et al. *J Clin Oncol.* 2021; 39:2294-303; 4. Smith MR, et al. *Eur Urol.* 2021; 79: 150-8;

5. Bryce AH, et al. *Prostate Cancer Prostatic Dis.* 2017;20(2):221-7.

ADT, androgen deprivation therapy; ARPI, androgen receptor pathway inhibitor; CRPC, castration-resistant prostate cancer; CSPC, castration-sensitive prostate cancer; PSA, prostate-specific antigen; PSA-PD, PSA progression prior or concurrently to radiographic progression; R-PD, radiographic progression without prior or concurrent PSA progression.



## NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX

# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## METHODS

- A retrospective analysis of two phase 3 trials comparing APA + ADT vs PBO + ADT were conducted separately:
  - TITAN (NCT02489318): in 1052 patients with mCSPC<sup>1</sup>
  - SPARTAN (NCT01946204): in 1027 patients with nmCRPC<sup>2</sup>
- Based on their clinical outcomes in the TITAN and SPARTAN studies, patients were categorized as:
  - **R-PD:** radiographic progression without prior or concurrent PSA progression
  - **PSA-PD:** PSA progression prior or concurrently to radiographic progression
  - **NO-PD:** No PSA progression, radiographic progression, or death
  - **DEATH:** Death before any progression

1. Chi KN, et al. *N Engl J Med.* 2019; 381:13-24; 2. Smith MR, et al. *N Engl J Med.* 2018; 378:1408-18.

ADT, androgen deprivation therapy; APA, apalutamide; mCSPC, metastatic castration-sensitive prostate cancer; nmCRPC, non-metastatic castration-resistant prostate cancer; PBO, placebo; PSA, prostate-specific antigen.



## NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX

# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## METHODS

- Distribution of type of progression, baseline clinical features, and site of radiographic progression in R-PD were assessed
- Time to radiographic progression in R-PD patients and time to PSA progression in PSA-PD patients were compared between treatment groups
- Biomarker analysis:
  - Decipher prostate test by Veracyte was performed on 198 (18.8%) TITAN and 233 (19.3%) SPARTAN primary tumors<sup>1</sup>
  - Gene expression signatures were explored. Classification models were built using Ridge regression to predict the response category
- Overall survival of R-PD, PSA-PD, and NO-PD patients were compared
- Time-to-event end points were analyzed by Kaplan-Meier method
- HR (95% CI) and p values were estimated using Cox proportional hazard models

1. Erho N, et al. *PLoS One*. 2013;8(6):e66855.

HR, hazard ratio; NO-PD, No PSA progression, radiographic progression, or death; PSA, prostate-specific antigen; PSA-PD, PSA progression prior or concurrently to radiographic progression. R-PD, radiographic progression without prior or concurrent PSA progression.



## NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX

# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## RESULTS

- TITAN study (N=1052): 130 (12.4%) patients were R-PD, 433 (41.2%) PSA-PD, 469 (44.6%) NO-PD, and 20 (1.9%) DEATH
- SPARTAN study (N=1207): 125 (10.4%) patients were R-PD, 548 (45.4%) PSA-PD, 526 (43.6%) NO-PD, and 8 (0.7%) DEATH

**TABLE 1: Patient disposition by progression outcome**

	TITAN (mCSPC)		SPARTAN (nmCRPC)	
	APA+ADT n=525	PBO+ADT n=527	APA+ADT n=806	PBO+ADT n=401
<b>R-PD</b>	64 (12.2%)	66 (12.5%)	95 (11.8%)	30 (7.5%)
<b>PSA-PD</b>	125 (23.8%)	308 (58.4%)	224 (27.8%)	324 (80.8%)
<b>NO-PD</b>	324 (61.7%)	145 (27.5%)	480 (59.6%)	46 (11.5%)
<b>DEATH</b>	12 (2.3%)	8 (1.5%)	7 (0.9%)	1 (0.2%)

APA+ADT, apalutamide + androgen deprivation therapy; DEATH, death before any progression; mCSPC, metastatic castration-sensitive prostate cancer; NO-PD, no PSA progression or radiographic progression or death; nmCRPC, non-metastatic castration-resistant prostate cancer; PBO+ADT, placebo + androgen deprivation therapy; PSA, prostate specific antigen; PSA-PD, PSA progression prior or concurrently to radiographic progression; R-PD, radiographic progression without prior or concurrent PSA progression.

### NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

**RESULTS**

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX



# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## RESULTS

**TABLE 2: Baseline clinical characteristics (Apalutamide ITT population; TITAN and SPARTAN)**

	TITAN (mCSPC), APA+ADT				SPARTAN (nmCRPC), APA+ADT			
	R-PD n=64	PSA-PD n=125	NO-PD n=324	DEATH n=12	R-PD n=95	PSA-PD n=224	NO-PD n=480	DEATH n=7
PSA (ng/mL), median (range)	8.7 (0.0; 993.4)	13.09 (0.1; 2256.0)	4.23 (0.0; 2682.0)	25.68 (2.6; 901.7)	8.6 (0.8; 75.7)	14.46 (0.3; 294.8)	5.7 (0.1; 111.9)	12.2 (4.7; 109.0)
ECOG PS score=1	28 (43.8%)	54 (43.2%)	110 (34.0%)	5 (41.7%)	29 (30.5%)	50 (22.3%)	102 (21.3%)	2 (28.6%)
Gleason score at initial diagnosis					92	216	471	5
<8	19 (29.7%)	33 (26.4%)	117 (36.1%)	5 (41.7%)	52 (56.5%)	114 (52.8%)	273 (58.0%)	4 (80.0%)
≥8	45 (70.3%)	92 (73.6%)	207 (63.9%)	7 (58.3%)	45 (43.5%)	102 (47.2%)	198 (42.0%)	1 (20.0%)
Extent of disease at study entry								
Bone + only lymph node	22 (34.4%)	50 (40.0%)	88 (27.2%)	3 (25.0%)				
Bone + other organ(s) excluding visceral	4 (6.3%)	9 (7.2%)	3 (0.9%)	1 (8.3%)				
Bone + visceral and/or other organ(s)	13 (20.3%)	15 (12.0%)	25 (7.7%)	3 (25.0%)				
Number of bone lesions at study entry								
>10	28 (43.8%)	80 (64.0%)	93 (28.7%)	6 (50.0%)				
>5	35 (54.7%)	98 (78.4%)	145 (44.8%)	8 (66.7%)				
High volume	49 (76.6%)	103 (82.4%)	163 (50.3%)	10 (83.3%)				

**TABLE 3: Sites of progression in R-PD patients**

	TITAN (mCSPC)		SPARTAN (nmCRPC)	
	APA+ADT n=525	PBO+ADT n=527	APA+ADT n=806 <sup>a</sup>	PBO+ADT n=401
Bone only	31 (5.9%)	35 (6.6%)	9 (1.1%)	3 (0.7%)
No bone	32 (6.1%)	31 (5.9%)	79 (9.8%)	27 (6.7%)
Both	1 (0.2%)	0	0	0

<sup>a</sup>Missing characterization for 7 (0.9%) R-PD patients in SPARTAN, APA+ADT. APA+ADT, apalutamide + androgen deprivation therapy; DEATH, death before any progression; ECOG PS, Eastern Cooperative Oncology Group Performance Status; mCSPC, metastatic castration-sensitive prostate cancer; NO-PD, no PSA progression, radiographic progression, or death; nmCRPC, non-metastatic castration-resistant prostate cancer; PSA, prostate-specific antigen; PSA-PD, PSA progression prior or concurrently to radiographic progression; R-PD, radiographic progression without prior or concurrent PSA progression.

Please refer to Supplementary Table 1 for placebo group data.

### NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX





# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

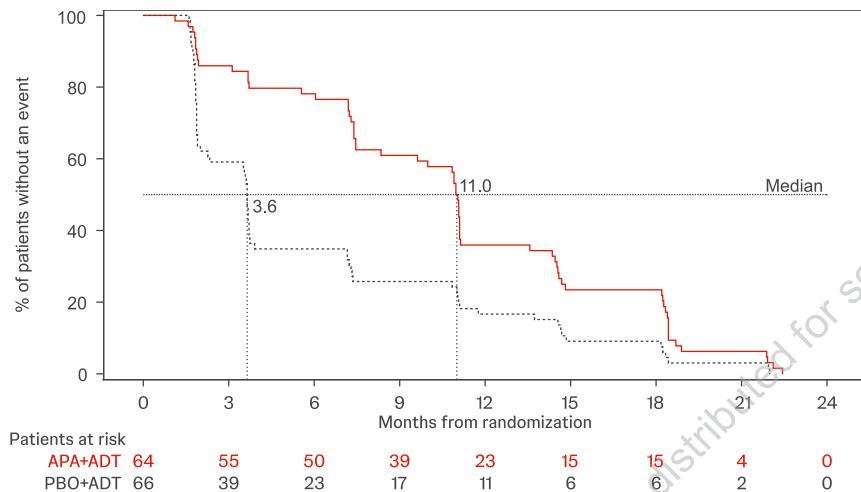
Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## RESULTS

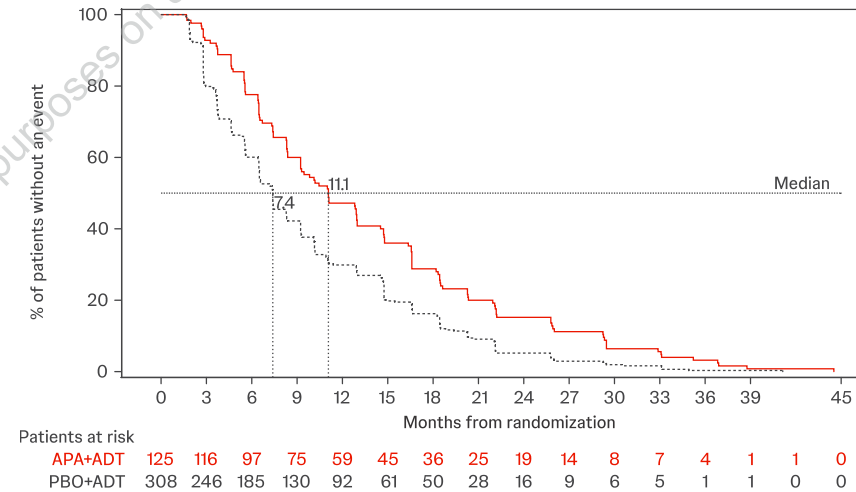
**FIGURE 1: Time to radiographic progression in R-PD patients**

- Compared with placebo, treatment with APA delayed the time to radiographic progression in R-PD patients (TITAN: HR, 0.51; 95% CI, 0.36–0.73, P=0.0003; SPARTAN: HR, 0.17; 95% CI, 0.1–0.28, P<0.0001) (Figure 1)
- Furthermore, treatment with APA delayed the time to PSA progression in PSA-PD patients (TITAN: HR, 0.61; 95% CI, 0.49–0.75; P<0.0001; SPARTAN: HR, 0.22; 95% CI, 0.18–0.27; P<0.0001) (data not shown)

**(A) TITAN (mCSPC)**



**(B) SPARTAN (nmCRPC)**



APA+ADT, apalutamide + androgen deprivation therapy; mCSPC, metastatic castration-sensitive prostate cancer; nmCRPC, non-metastatic castration-resistant prostate cancer; PBO+ADT, placebo + androgen deprivation therapy; R-PD, radiographic progression without prior or concurrent PSA progression.

### NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX



# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## RESULTS

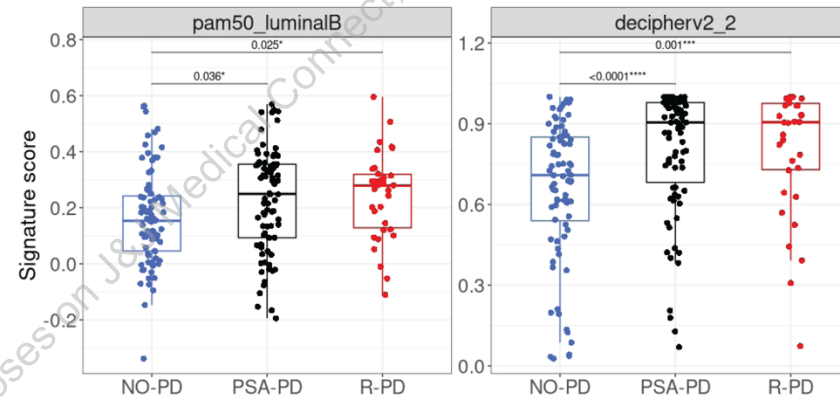
### FIGURE 2: Gene expression signatures and patient classification for TITAN (mCSPC)

- Increased luminal B lineage and decipher risk signatures were observed in R-PD and PSA-PD vs NO-PD patients for TITAN (n=196; Figure 2A); equivalent signature scores were observed in NO-PD, PSA-PD, and R-PD patients for SPARTAN (n=233; data not shown)
- A transcriptomic classification model achieved moderate discrimination between R-PD or PSA-PD vs NO-PD patients for TITAN, (n=196; Figure 2B), while no discrimination of R-PD alone was observed; poor discrimination was observed for SPARTAN (n=233)
- Additional biomarker analysis using genomic and proteomic data is underway

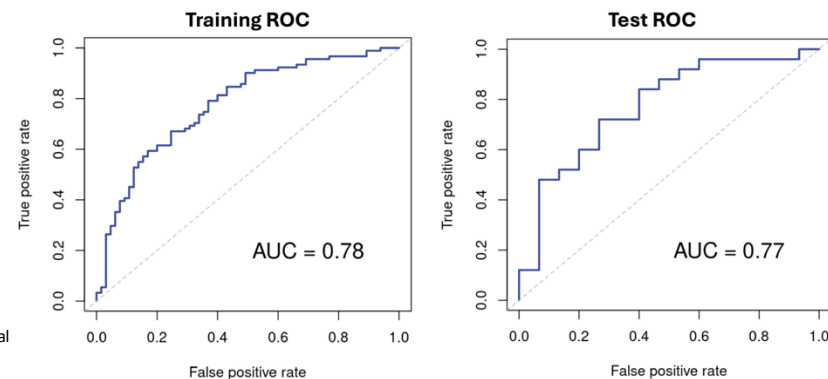
AUC, area under the curve; mCSPC, metastatic castration-sensitive prostate cancer; NO-PD, no PSA progression, radiographic progression, or death; PSA-PD, PSA progression prior or concurrently to radiographic progression; Ref, reference; ROC, receiver operating characteristic; R-PD, radiographic progression without prior or concurrent PSA progression.

Note: n=2 patients from the TITAN study with Decipher test results were excluded due to death before any progression. **A.** Left plot shows luminal B and right shows decipher signature-based scores. **B.** P-values in the signature plots were calculated using Wilcoxon test with multiple comparison correction by Holm method. Left ROC is on training data and right test data.

### (A) Luminal B and decipher risk signature scores



### (B) Classification of R-PD, PSA-PD vs NO-PD patients



## NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX



# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

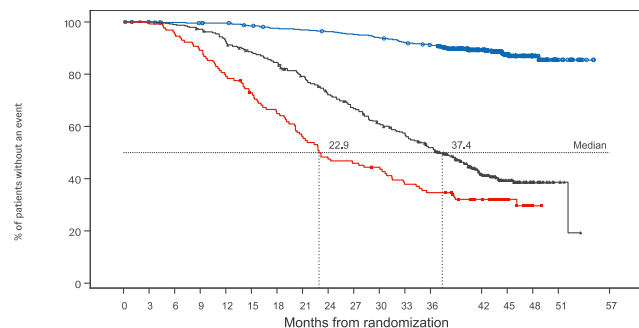
Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## RESULTS

**FIGURE 3: Overall survival by progression outcome**

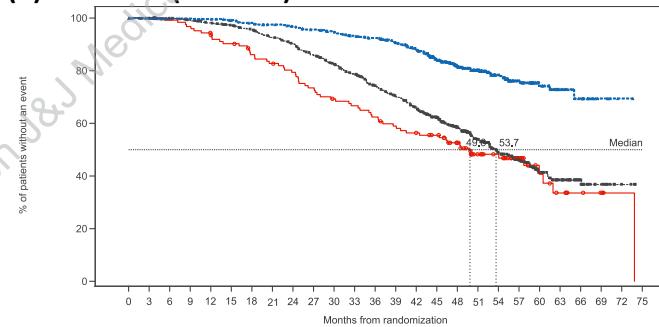
- R-PD patients had shorter OS compared to PSA-PD patients in both studies (median OS: R-PD vs PSA-PD: 22.9 months vs 37.4 months in the TITAN study; 49.8 months vs 53.7 months in the SPARTAN study)

**(A) TITAN (mCSPC)**



Patients at risk	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57
R-PD	130	129	123	115	102	92	82	71	60	58	55	47	43	37	30	16	2	0	0	0
PSA-PD	433	433	428	419	397	378	358	332	301	278	251	233	209	166	117	66	25	5	0	0
NO-PD	469	466	462	460	458	451	445	442	438	433	427	418	411	366	261	159	68	20	3	0

**(B) SPARTAN (nmCRPC)**



Patients at risk	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60	63	66	69	72	75
R-PD	125	125	123	120	115	110	103	99	94	87	81	78	73	68	64	61	51	37	33	21	12	8	5	3	1	0
PSA-PD	548	548	545	538	528	516	503	483	466	440	415	390	359	335	308	273	228	185	139	110	65	44	24	12	4	0
NO-PD	526	513	493	490	486	478	472	465	458	451	442	432	424	407	385	315	253	208	150	104	61	32	18	5	1	0

	TITAN (mCSPC)			
	HR (95% CI)	P-value	Events	Median (95% CI), months
R-PD	1.56 (1.22-1.99)	0.0004	66.9% (87/130)	22.9 (20.2-30.9)
PSA-PD	1.00 (Ref.)	-	56.4% (244/433)	37.4 (33.7-40.3)
NO-PD	0.14 (0.11-0.19)	<0.0001	11.5% (54/469)	NE (NE-NE)

	SPARTAN (nmCRPC)			
	HR (95% CI)	P-value	Events	Median (95% CI), months
R-PD	1.23 (0.94-1.62)	0.1289	52.8% (66/125)	49.8 (38.6-60.5)
PSA-PD	1.00 (Ref.)	-	47.1% (258/548)	53.7 (50.3-57.8)
NO-PD	0.35 (0.27-0.44)	<0.0001	18.3% (96/526)	NE (NE-NE)

CI, confidence interval; HR, hazard ratio; NE, not estimable; mCSPC, metastatic castration-sensitive prostate cancer; nmCRPC, non-metastatic castration-resistant prostate cancer; NO-PD, no PSA progression, radiographic progression, or death; PSA-PD, PSA progression prior or concurrently to radiographic progression; Ref, reference; R-PD, radiographic progression without prior or concurrent PSA progression.

### NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX



# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## RESULTS

**SUPPLEMENTARY TABLE 1: Baseline clinical characteristics (Placebo ITT population; TITAN and SPARTAN)**

	TITAN (mCSPC), PBO+ADT			
	R-PD (n=66)	PSA-PD (n=308)	NO-PD (n=145)	DEATH (n=8)
PSA (ng/mL), median (range)	9.82 (0.0; 2228.5)	5.13 (0.0; 1882.0)	2.08 (0.0; 802.9)	32.94 (0.3; 1312.5)
ECOG PS score=1	23 (34.8%)	113 (36.7%)	40 (27.6%)	2 (25.0%)
Gleason score at initial diagnosis				
<8	25 (37.9%)	81 (26.3%)	60 (41.4%)	3 (37.5%)
≥8	41 (62.1%)	227 (73.7%)	85 (58.6%)	5 (62.5%)
Extent of disease at study entry				
Bone + only lymph node	21 (31.8%)	101 (32.8%)	43 (29.7%)	1 (12.5%)
Bone + other organ(s) excluding visceral	5 (7.6%)	11 (3.6%)	4 (2.8%)	0
Bone + visceral and/or other organ(s)	16 (24.2%)	42 (13.6%)	11 (7.6%)	3 (37.5%)
Number of bone lesions at study entry				
>10	35 (53.0%)	130 (42.2%)	28 (19.3%)	3 (37.5%)
>5	45 (68.2%)	182 (59.1%)	51 (35.2%)	4 (50.0%)
High volume	55 (83.3%)	206 (66.9%)	69 (47.6%)	5 (62.5%)
	SPARTAN (nmCRPC), PBO+ADT			
	R-PD (n=30)	PSA-PD (n=324)	NO-PD (n=46)	DEATH (n=1)
PSA (ng/mL), median (range)	5.83 (1.1; 112.2)	8.66 (1.2; 291.8)	5.04 (1.5; 54.5)	28.68 (28.7; 28.7)
ECOG PS score=1	6 (20.0%)	76 (23.5%)	6 (13.3%)	1 (100%)
Gleason score at initial diagnosis	29	314	43	1
<8	14 (48.3%)	182 (58.0%)	22 (51.2%)	0
≥8	15 (51.7%)	132 (42.0%)	21 (48.8%)	1 (100%)

DEATH, death before any progression; ECOG PS, Eastern Cooperative Oncology Group Performance Status; mCSPC, metastatic castration sensitive prostate cancer; NO-PD, no PSA progression or radiographic progression or death; nmCRPC, non-metastatic castration resistant prostate cancer; PBO+ADT, placebo + androgen deprivation therapy; PSA, prostate specific antigen; PSA-PD, PSA progression prior or concurrently to radiographic progression; R-PD, radiographic progression without prior or concurrent PSA progression.

### NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX



# Radiographic Progression Without PSA Progression (R-PD) in Advanced Prostate Cancer Patients

Ruchi Chaudhary,<sup>1</sup> Amitabha Bhaumik,<sup>2</sup> Neeraj Agarwal,<sup>3</sup> Kristin Shotts,<sup>1</sup> Angela Lopez-Gitlitz,<sup>4</sup> Sharon McCarthy,<sup>2</sup> Suneel Mundle,<sup>2</sup> Kim N. Chi,<sup>5</sup> Eric J. Small<sup>6,7</sup>

## APPENDIX

### REFERENCES:

1. Chi KN, et al. *N Engl J Med.* 2019; 381:13-24;
2. Smith MR, et al. *N Engl J Med.* 2018; 378:1408-18;
3. Chi KN, et al. *J Clin Oncol.* 2021; 39:2294-303;
4. Smith MR, et al. *Eur Urol.* 2021; 79: 150-8;
5. Bryce AH, et al. *Prostate Cancer Prostatic Dis.* 2017;20(2):221-7;
6. Erho N, et al. *PLoS One.* 2013;8(6):e66855.

### DISCLOSURES:

**RC, AB, KS, ALG, SMcc, and SM** are full-time employees of Johnson & Johnson and may own company stock. **NA** has received consultancy fees from Astellas, AstraZeneca, Aveo, Bayer, Bristol Myers Squibb, Calithera, Clovis, Eisai, Eli Lilly, EMD Serono, Exelixis, Foundation Medicine, Genentech, Gilead, Janssen, Merck, MEI Pharma, Nektar, Novartis, Pfizer, Pharmacyclics, and Seattle Genetics; research funding (payment to institution) from Astellas, AstraZeneca, Bavarian Nordic, Bayer, Bristol Myers Squibb, Calithera, Celldex, Clovis, Eisai, Eli Lilly, EMD Serono, Exelixis, Genentech, Gilead, Glaxo Smith Kline, Immunomedics, Janssen, Medivation, Merck, Nektar, New Link Genetics, Novartis, Pfizer, Prometheus, Rexahn, Roche, Sanofi, Seattle Genetics, Takeda, and Tracoon. **KNC** reports research grants (payment to institution) from Astellas, AstraZeneca, Janssen, Merck, Novartis, Pfizer, Point Biopharma, Roche, and Sanofi; consulting fees from Astellas, AstraZeneca, Janssen, Merck, Novartis, Pfizer, Point Biopharma, Roche, and Sanofi; payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from Astellas, AstraZeneca, Janssen, Merck, Novartis, Pfizer, Point Biopharma, Roche, and Sanofi; payment for expert testimony from AstraZeneca, Janssen, Merck, and Novartis. **EJS** reports consultancy to Fortis and Janssen; research funding (self) from Janssen, Merck Sharp & Dohme; and being a shareholder in Fortis and Harpoon Therapeutics.

### ACKNOWLEDGMENTS:

The authors thank the study patients and investigators for their participation. Priya Ganpathy, MPH CMPP (SIRO Clinpharm UK Limited) provided medical writing assistance and Jennifer Han, MS (Johnson & Johnson) provided additional editorial support. Sandeep Chavan (SIRO Medical Writing Pvt. Ltd., India) provided graphic designing support.

**FUNDING:** This study was funded by Johnson & Johnson.

### NAVIGATION



KEY TAKEAWAY

CONCLUSIONS

INTRODUCTION

METHODS

Assessments & Analysis

RESULTS

Clinical Characteristics & Sites of Progression

Time to Radiographic Progression

Biomarker Analysis

Overall Survival

Supplementary Table 1

APPENDIX

