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## 36th INTERNATIONAL PROSTATE CANCER UPDATE™

**February 1–4, 2026**
**Vail, Colorado**

# Poster Abstracts

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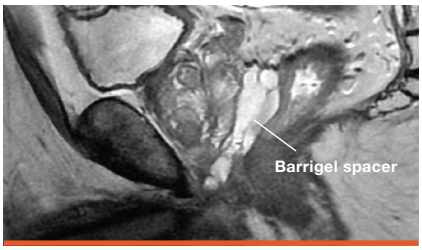


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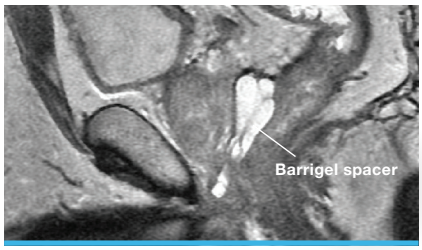


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**REFERENCES: 1.** Mariados NF, Orio PF III, King MT et al. *JAMA Oncol* (2023).* **2.** King MT, Svatos M, Orio PF III et al. Pract Radiat Oncol (2023).* **3.** Svatos M, Chell E, King MT et al. *Med Phys* (2024).* **4.** Gejerman G, Goldstein MM, Chao M et al. *Pract Radiat Oncol* (2023).** **5.** Williams J, Mc Millan K, Chao M et al. *J Med Imag Radiat Sci* (2022).


*Study sponsored by Palette Life Sciences, now part of Teleflex.
**Drs Gejerman, Chao, Lederer, and Orio are paid consultants of Palette Life Sciences, now part of Teleflex.

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# CONTENTS

## Abstract 001

### Water Vapor Therapy for The Management of Prostate Cancer: The VAPOR 2 Study: Initial Report

Eric Gielser, MD, Arvin George, MD

Urology Austin, Austin, TX, USA

**Introduction:** The VAPOR 2 Study is a multicenter trial using a transurethral thermal water vapor device (Vanquish) to manage localized intermediate-risk prostate cancer. This data represents 110 treated patients with a minimum of 12-month follow-up reported.

**Methods:** A transurethral, ultrasound guided thermal water vapor device was used to convectively ablate targeted prostate tissue in any location or anatomic prostate zone. A total of 235 patients were treated at 26 sites. Treatment strategy included ablating an MRI visible lesion and a minimum of a 1cm intraprostatic margin. Patients completed a targeted and sector fusion biopsy at 6 months.
Patients with a single PI-RADS 3 or 4 target and GG2, confirmed by fusion biopsy, PSA <15ng/ml, and no MRI evidence of ECE were included.

**Results:** 108 patients underwent a 6-month biopsy with 91% (98/108) infield biopsies negative for ≥GG2 disease following a single procedure. Consistent results were observed across all locations of the prostate. For target distance from the apex, there was no statistical difference based on lesion location (p=.99; Fisher's Exact). Additionally, there was no statistical difference based on anterior, lateral, or posterior lesion position (p=.87; Fisher's Exact).
PSA reduced by 52% from 6.3ng/ml [1.5, 14.9] (n=110) at baseline to 3.0ng/ml [0.3, 15.6] (n=108) at 1 year.
Prostate volume reduced by 21% from 42.9cc [20.1, 79.6] (n=110) at baseline to 34.3cc [10.6, 73.6] (n=110) at 6 months.
92% (101/110pts) did not require recatheterization. The mean catheterization time was 5 days (protocol minimum 3 days). There was no long term-term urinary retention.
No device related serious adverse events (SAE's) were reported. There were 5 procedure-related SAE's, all resolved by 12 months. At 12 months, there were 3 patients (2.7%) with ongoing Grade 2 urinary incontinence (UI) and no ≥Grade 3 UI events reported. New or worsening ED was reported in 18/110 (16.4%) of subjects at one year.

**Conclusions:** This initial report shows a 91% clearance of targeted MRI visible ≥GG2 disease following a single treatment, and the ability to effectively treat anywhere in the prostate. Excellent short term oncologic control and 1-year safety profile with no device related SAE's and low morbidity was achieved. This study is ongoing with a 3-year analysis planned to support management of prostate cancer on 235 treated subjects.

# Abstract 002

## Exploring PSA Reduction After IRE Treatment in Prostate Cancer

Christopher Edwards[1], Jessica Ramirez[2], Edward Wu1, Arsha Venkat[1], Michael West[1], Navid Leelani[1], Yitzchak E Katlowitz[1], Ariel Schulman[1], David Silver[1]

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**Introduction and Objective:** Irreversible electroporation (IRE) is a non-thermal ablation technique that can be used in focal therapy for the ablation of prostate tissue. This study evaluates the impact of ablation pattern, Gleason score, and lesion location on prostate-specific antigen (PSA) reduction three months post-IRE in patients undergoing treatment for primary prostate cancer.

**Methods:** A total of 26 patients with primary prostate cancer treated IRE were included in this analysis. PSA levels were recorded at baseline and 12 months post-treatment. Gleason scores were recorded at baseline. Lesion locations were categorized as anterior, posterior, apex-mid, and base-mid; ablation patterns were categorized as lesion + margin, quadrant, subtotal and hemi. Patient characteristics can be found in Table 1. Change in PSA was calculated and analyzed using ANOVA to assess associations with ablation pattern, Gleason score, and lesion location. Tukey HSD post-hoc tests were performed for lesion location comparisons.

**Results:** The median (IQR) baseline PSA was 7.0 (2.1, 30.6) ng/mL, decreasing to a median of 1.0 (0.01, 12.5) ng/mL at 12 months, with a median PSA reduction of –4.3 (-28.6, 2.5) ng/mL. No significant differences in PSA change by ablation pattern (p=0.79) or Gleason score (p=0.89) were found. A statistically significant difference was observed for lesion location (p=0.0004); however, further analysis revealed no significant pairwise differences. The greatest median PSA reductions were observed in patients with anterior and base-mid treated-lesions (Figure 1).

**Conclusion:** IRE demonstrates PSA reduction across various ablation patterns and Gleason scores. While lesion location showed statistical significance in PSA change, post-hoc analysis did not confirm differences between lesion locations. These preliminary results support the utility of post-ablation PSA monitoring irrespective of IRE ablation pattern or lesion location.

**Table 1. Primary IRE Patient Characteristics**

| COHORT | IRE-Treated (n=26) |
|---|---|
| Baseline PSA, median (IQR) | 7.0 (2.1, 30.6) |
| 12-Month PSA, median (IQR) | 1.0 (0.01, 12.5) |
| Gleason Score | |
| 3+4 | 16 |
| 4+3 | 9 |
| 4+4 | 1 |
| Lesion Location, n | |
| Anterior | 7 |
| Posterior | 13 |
| Apex-Mid | 4 |
| Base-Mid | 2 |
| Ablation Patter, n | |
| Lesion + Margin | 3 |
| Quadrant | 18 |
| Subtotal | 1 |
| Hemi | 4 |

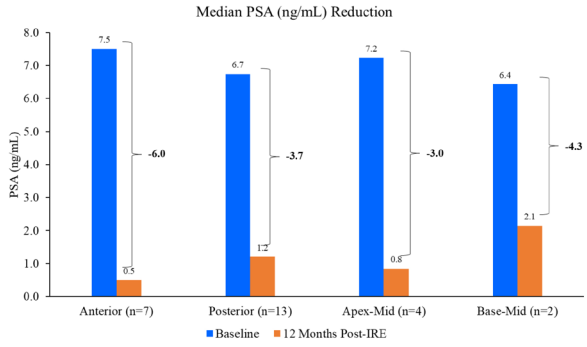


**Figure 1. Median PSA (ng/mL) Reduction**

## Abstract 003

### Phase 3 study of $^{68}$Ga-PSMA-11 PET combined with MRI for the detection of prostate cancer (BIPASS)

Clint Bahler[1], Jeremie Calais[2], Louise Emmett[3], Timothy McClure[4], Sanoj Punnen[5], Preston Sprenkle[6], Karol Osipowicz[7], David Liu[7]*

[1]Indiana University, [2]UCLA, [3]St Vincent's Hospital, Sydney, [4]Weill Cornell, [5]University of Miami, [6]Yale University, [7]Telix Pharmaceuticals Limited, Melbourne

**Background:** Prostate cancer (PCa) is diagnosed through directed and template/anatomical biopsy based on clinical and radiographic suspicion. In patients presenting with high risk of PCa, anatomically-directed biopsies are performed to identify occult disease, which can lead to anxiety, complications, financial burden, and logistical challenges. Biopsy of the Prostate Avoidance Stratification Study (BiPASS) is a Phase 3 study evaluating the diagnostic performance of combining 68Ga-PSMA-11 PET and MRI targeted biopsy for the detection of PCa, using histopathological confirmation as the standard of truth.

**Methods:** This Phase 3, single-arm, multicenter, prospective, open-label, longitudinal study (NCT07052214) will enroll 204 patients ≥18 years with clinical suspicion of PCa who have not undergone prior prostate biopsy and are scheduled to undergo template biopsy based on initial MRI within 3 months before enrollment (PI-RADS 1-4). Key exclusion criteria include prior treatment of PCa, diagnosis of PCa, or obvious metastatic disease on prior imaging.

All patients will undergo 68Ga-PSMA-11 & MRI scans, followed by standard template biopsy. PSMA and MRI scans will be interpreted by 3 blinded readers. MRI- & PSMA-targeted biopsies will be performed with 2 cores per lesion. If PCa is histopathologically identified, lesion linking with imaging will be performed with no further follow-up required. Follow-up data will be collected for up to 6m for patients with no baseline imaging or histopathological evidence of PCa. Additional imaging & targeted biopsies may be performed during follow-up period at the investigator's discretion. Any additional biopsy, imaging, clinical, histological, genetic, & intervention data will contribute to the determination of the SOT. Follow-up will provide longitudinal surveillance to ensure that patients initially evaluated as negative for PCa on both imaging & histopathology are reliably negative.
The co-primary endpoints are sensitivity and specificity of combining PSMA PET- & MRI- targeted biopsy for detection of PCa, calculated by comparing diagnostic findings to histopathological or composite SOT. Key secondary endpoints include detection performance (sensitivity, specificity, PPV, NPV, accuracy, & misclassification rate) of PSMA PET- & MRI- targeted biopsy for detection of PCa & interobserver variability of PSMA PET interpretation.

**Results:** This study is ongoing; no results are available at the time of abstract submission.

**Conclusion:** PSMA PET combined with MRI for targeted biopsy may improve the detection of clinically significant PCa and treatment management, minimize cost and procedural risk, de-escalate the number of biopsies, and potentially eliminate the need for systematic/template/saturation biopsies in select populations.

## Abstract 004

### SOLACE: A Phase 1 Pharmacokinetic, Dosimetry, Safety, and Dose Optimization Study for a Single Dose of 153Sm-DOTMP to Treat Metastatic Bone Pain

Ebrahim Delpassand[1], Julian Peguero[2], Harsha Doddihal[3], David Cade[3]*, Oliver Sartor[4]

[1]Excel Diagnostics and Nuclear Oncology Center, [2]Oncology Consultants, [3]Telix Pharmaceuticals, [4]LCMC Health.

**Background:** With patients with bone metastases commonly report pain and significant degradations in quality of life, current treatment options have limitations. Patients may not experience effective relief, and treatments often cause myelotoxicity and high costs. Bone pain is one of the most common forms of pain reported by patients with metastatic disease and significantly degrades quality of life.

DOTMP is a bone-seeking chelating agent, and when radiolabeled with samarium-153 ($^{153}$Sm-DOTMP) is a therapeutic radiopharmaceutical that emits both beta particles and gamma photons to bone metastases. Prior Phase I experience (QSAM-101, n=5) demonstrated no DLTs, manageable hematologic toxicity, and early signals of pain relief. The Phase 1 Samarium Optimized for Long-lasting Analgesia in Cancerous End-stage bone pain (SOLACE) study aims to evaluate pharmacokinetics (PK), dosimetry, safety, and efficacy of a single dose of $^{153}$Sm-DOTMP for the treatment of pain associated with metastatic bone cancer.

**Methods:** This open-label, Phase 1 study (NCT07197645) includes dose escalation (Part A, n=9-15, up to 3 cohorts) and dose selection (Part B, n=18) in patients with painful metastatic bone lesions. In Part A, 3 patients per cohort will be enrolled in parallel into Cohort 1 and 2 and will receive 0.5 mCi/kg or 1.0 mCi/kg of intravenous $^{153}$Sm-DOTMP, respectively. (Cohort 1: 0.5 mCi/kg; Cohort 2: 1.0 mCi/kg; Cohort 3: 1.5 mCi/kg). If no dose-limiting toxicities (DLTs) are seen in Cohort 2, 3 patients will be enrolled in Cohort 3 (1.5 mCi/kg intravenous 153Sm-DOTMP). Cohorts 2 and 3 will enroll 3 additional participants if only 1/3 patients had DLT at that cohort; if ≥2 DLTs are seen, no further patients will be recruited at that dose level, and it will be declared a non-tolerated dose. The DLT observation period will be 6 weeks after administration, during which safety and tolerability will be closely monitored. Part B includes a randomized cohort expansion at 2 dose levels based on Part A.

Eligible patients will be aged ≥18 years with histologically confirmed malignancy with multiple metastatic bone lesions including ≥1 confirmed painful (pain score of ≥4 on Numeric Rating Scale 11 [NRS-11]) osteoblastic bone tumor that exhibits avid update as shown by $^{99m}$Tc-diphosphonate bone scans ≤60 days of 153Sm-DOTMP administration. Patients will have had disease progression while on anti-cancer treatment or ineligible for such treatments with painful bone lesions not amenable to palliative EBRT. Patients must have been receiving a stable regimen of bisphosphonates and/or hormonal or endocrine therapy for ≥3 months prior to $^{153}$Sm-DOTMP administration.

Part A primary endpoints are adverse events and incidence of DLTs, PK, and cumulative radiation doses of $^{153}$Sm-DOTMP. Part B primary endpoints are the identification of optimal dose of $^{153}$Sm-DOTMP, reduction in weekly NRS-11 pain scores, and change in daily oral morphine equivalent dose from baseline.

## Abstract 005

### Effective Resolution Of Bone Metastases In Subjects with Metastatic Prostate Cancer Using Sync-T Therapy SV-102

Ngwa-Ebogo TT, Mbouche LO, Manka'a ML, Eyongeta DE, Bityouma MDC, Angwafo III FF

Gerald Andriole, MD[1], Charles J. Link, MD[1,2], Stephen Kee, MD[1], Lucinda Gamble, MS[1], Renata Barco, MD[3], Daniel K. Recinella, MBA[1], David J Vaughan, MD[1], Richard G Harris, MD[1,4], Eduardo Cortes[5], Jason R. Williams, MD[5], Carlos A Vargas, MD[3]

**Background:** Conventional immunotherapy for metastatic prostate cancer has limited efficacy and relatively high rates of severe immune-related adverse events. SYNC-T is a novel in situ therapy that synchronizes the presence of tumor antigens, an immune therapy drug, and immune cells in the tumor microenvironment and locoregional lymph nodes.
SYNC-T Therapy SV-102 combines device-induced partial cryolysis of a targeted tumor to create a personalized multi-antigen vaccine, followed immediately by intratumoral infusion of SV-102, leading to T-cell activation and an effective systemic anti-tumor response. SV-102 is comprised of four immune modulators: a PD-1 inhibitor, CTLA-4 inhibitor, CD40 agonist, and TLR9 agonist. Herein we report on the first 15 subjects treated with SYNC-T Therapy SV-102.

**Methods:** Fifteen men with metastatic PCa (10 failed hormone therapy and 5 refused hormone therapy) were recruited into a single-arm phase 1 study (NCT05544227). Other prior therapies included chemotherapy, immunotherapy, and/or radiation therapy. All were treated, evaluable and received the same dose of SV-102. All underwent SYNC-T Therapy q4 weeks for up to 12 cycles (median = 6). The primary prostate tumor was treated in all men in an outpatient procedure using a TRUS-guided transperineal approach.

**Results:** Median age was 61 (48-74). At baseline, 13/15 (87%) had skeletal metastases (range 1-54), of which 5/13 (38%) had >20 lesions. After therapy, all skeletal metastases resolved in 7/13 (54%) patients. Through May 1, 2025, 4 of those 7 (57%) subjects have ongoing response. For the entire cohort, there were 8 (53%) CRs and 5 (33%) PRs for an ORR of 87%. Median time to response was 2.9 months; median duration of response was 12.1 months (range 1.1-24.1). Median rPFS was 14.2 months (range 4.8- 24.1). Median OS has not been reached (range 6.1 to 24.6 months). Three men died during follow-up, resulting in 80% survival at 17.2 months median follow-up. SYNC-T Therapy was well-tolerated with 41 TEAEs in 13 subjects. The majority (95%) of TEAEs were Grade 1 or 2, most commonly fever and hematuria. There were 2 Grade 2 irAEs and 2 Grade 3 TEAEs.

**Conclusions:** These data demonstrate initial proof of concept that prostate cancer bone metastases can be effectively treated by partial cryolysis of the primary tumor combined with intratumoral infusion of immunotherapeutic SV-102. SYNC-T Therapy SV-102 exhibited an acceptable safety profile and is being further evaluated in a phase 2 multi- center US trial. SYNC-T Therapy SV-102 potentially expands the role of urologists in treating patients with advanced metastatic prostate cancer.

## Abstract 006

### Real-World Comparison of Overall Survival In Patients with Metastatic Castration-Sensitive Prostate Cancer Initiating Apalutamide Without Docetaxel Versus Darolutamide Without Docetaxel

Benjamin Lowentritt[1], Mehmet A. Bilen[2], Mukul Singhal[3], Carmine Rossi[4], Dominic Pilon[4], Courtney D. Morrow[3], Gordon Brown[5]

[1]Chesapeake Urology, Towson, MD, [2]Winship Cancer Institute of Emory University, Atlanta, GA, [3]Johnson & Johnson, Horsham, PA, USA, [4]Analysis Group, Inc., Montréal, Canada, [5]New Jersey Urology, Cherry Hill, NJ

**Background:** Apalutamide and darolutamide are androgen receptor pathway inhibitors (ARPIs) approved for metastatic castration-sensitive prostate cancer (mCSPC) in combination with androgen deprivation therapy (ADT). The darolutamide without docetaxel registrational trial did not meet its overall survival (OS) endpoint; however, apalutamide demonstrated significantly OS improvement. While real-world evidence demonstrated treatment with apalutamide improved OS versus other ARPIs in combination with ADT for mCSPC, no head-to-head studies have compared apalutamide and darolutamide without docetaxel. This study assessed OS by 24 months in ARPI-naïve mCSPC patients initiating apalutamide or darolutamide, both without docetaxel.

**Methods:** A longitudinal, retrospective cohort study was conducted to assess OS by 24 months in ARPI-naïve patients with mCSPC from linked clinical data from private, community-based urology practices (PPS Analytics) and US claims data from the Komodo Research Database (1/1/2016–6/30/2025). The index date was defined as the first apalutamide or darolutamide dispensation or paid pharmacy claim on or after 8/5/2022 (i.e., the date of US Food and Drug Administration approval of darolutamide in mCSPC). Patients were required to have ≥12 months of pre-index clinical activity and classified as having mCSPC at ARPI initiation based on ≥1 diagnosis code or clinical indicator of metastasis in the absence of castration resistance, assessed from diagnosis codes, unstructured physician notes, and observed increases in prostate-specific antigen levels following medical or surgical castration. Patients were excluded if treated with docetaxel within 90 days prior to or within 30 days post-index date. Follow-up spanned from the index date to the latter of the end insurance claim or clinical activity. As an intention-to-treat approach was used, patients were not censored if they discontinued or switched off the index ARPI, initiated another advanced PC treatment or progressed to castration resistance. Pre-index characteristics were balanced between cohorts using inverse-probability of treatment weighting. Comparison of OS was conducted using weighted Cox proportional hazards models.

**Results:** Overall, 1,460 apalutamide patients without docetaxel (weighted characteristics: median age 74 years, 60% White, 22% Black, 80% Medicare-insured, mean Quan-CCI: 10.1) and 287 darolutamide patients without docetaxel (weighted characteristics: median age 74 years, 60% White, 22% Black, 81% Medicare-insured, mean Quan-CCI: 10.0) were identified. Median time between metastasis and ARPI initiation was 4.1 months in apalutamide patients and 2.9 months in darolutamide patients. Bone metastases were the most frequently diagnosed (apalutamide: 54%; darolutamide: 53%) and visceral metastases were diagnosed in 18% of apalutamide and 19% of darolutamide patients. By the pre-specified 24-month timepoint, apalutamide patients had a statistically significant 51% reduction in risk of death relative to darolutamide patients (hazard ratio [HR]: 0.49; 95% confidence interval [CI]: 0.30, 0.83]; P=0.007). Results were consistent when assessing OS using all follow-up (HR: 0.51; 95% CI: 0.32, 0.82).

**Conclusion:** In this study of ARPI-naïve patients with mCSPC, patients treated with apalutamide without docetaxel had significantly greater OS by 24 months compared with patients who initiated darolutamide without docetaxel. These findings highlight that apalutamide initiation is associated with an improved survival benefit relative to darolutamide, and without the need for treatment intensification with docetaxel, in patients with mCSPC.

## Abstract 007

### Comparison of Early and Deep Prostate-Specific Antigen Response in Real-World Patients with Metastatic Castration-Sensitive Prostate Cancer Treated with Apalutamide or Enzalutamide

Mehmet A. Bilen[1], Gordon Brown[2], Mukul Singhal[3], Carmine Rossi[4], Dominic Pilon[4], Courtney D. Morrow[3], Benjamin Lowentritt[5]

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**Background:** Apalutamide and enzalutamide are two androgen receptor pathway inhibitors (ARPIs) recommended as initial treatment for patients with metastatic castration-sensitive prostate cancer (mCSPC) in combination with androgen deprivation therapy. A reduction of ≥90% in prostate-specific antigen (PSA) levels from baseline (i.e., PSA90 response) is recognized as a critical early indicator of therapeutic efficacy. This study compared the achievement of PSA90 response by 6 months among patients with mCSPC initiating treatment with apalutamide or enzalutamide with a detectable pretreatment PSA (i.e., >0.2 ng/mL).

**Methods:** This study used a longitudinal, retrospective cohort design to compare PSA90 response by 6 months in patients with mCSPC treated with apalutamide and enzalutamide identified in linked clinical data from community urology practices (PPS Analytics) with U.S. claims data from the Komodo Research Database (1/1/2016–6/30/2025). Patients were classified into mutually exclusive treatment cohorts based on their first observed dispensation or paid pharmacy for apalutamide or enzalutamide on or after 12/16/2019 (i.e., date of US Food and Drug Administration approval of enzalutamide for mCSPC; index date). Patients were required to have ≥1 metastatic diagnosis and no evidence of castration resistance prior to or on the index date, which was assessed from structured notes in the urology data and from observed increases in PSA following medical or surgical castration. Patients were required to have ≥12 months of pre-index clinical activity and detectable PSA level as the most recent measurement within the 13-week period prior to or on the index date. Patients were observed from the index date and censored at the earliest of discontinuation of the index ARPI (using gap of >90 days), initiation of another ARPI, treatment with radiopharmaceuticals, or end of clinical activity. Pre-index characteristics were balanced between cohorts using inverse probability of treatment weighting. Comparison of PSA90 was conducted using weighted Cox proportional hazards models.

**Results:** Overall, 1,513 apalutamide patients (weighted characteristics: median age 74 years, 63% White, 82% Medicare, median baseline PSA 6.0 ng/ml) and 1,445 enzalutamide patients (weighted characteristics: median age 74 years, 62% White, 82% Medicare, median baseline PSA 6.2 ng/ml) were identified. Bone metastases were most frequently diagnosed (59% in both cohorts), 17% of all patients had visceral metastases, and 26% of all patients had metastases at multiple sites. Median time between metastasis and ARPI initiation was 1.8 months in both cohorts. By 6 months, 73.8% of apalutamide patients and 69.9% of enzalutamide patients achieved a PSA90 response (hazard ratio [HR]: 1.17; 95% confidence interval [CI]: 1.06, 1.30]; P=0.001). Results were consistent when assessing PSA90 using all follow-up (HR: 1.18; 95% CI: 1.08, 1.30). Median time to PSA90 response was numerically lower among apalutamide patients (2.8 months), relative to enzalutamide patients (3.2 months).

**Conclusions:** In this real-world study of patients with mCSPC treated with ARPIs, those initiating treatment with apalutamide achieved PSA90 response by 6 months at a significantly higher rate, compared to those initiating treatment with enzalutamide. These findings highlight that apalutamide initiation is associated with an improve rates of early, deep PSA90 response which may improve long-term survival prognosis.

# Abstract 008

## A Real-World Comparison of Deep Prostate-Specific Antigen Response in Patients with Metastatic Castration-Sensitive Prostate Cancer Initiated on Apalutamide or Abiraterone Acetate

Gordon Brown[1], Benjamin Lowentritt[2], Mukul Singhal[3], Frederic Kinkead[4], Dominic Pilon[4], Courtney D. Morrow3, Mehmet A. Bilen [5]

[1]New Jersey Urology, Cherry Hill, NJ; [2]Chesapeake Urology, Towson, MD; [3]Johnson & Johnson, Horsham, PA, USA; 4Analysis Group, Inc., Montréal, Canada; [5]Winship Cancer Institute of Emory University, Atlanta, GA

**Background:** Androgen receptor pathway inhibitors (ARPIs), including apalutamide and abiraterone acetate, are recommended first-line options, concomitantly with androgen deprivation therapy, for patients with metastatic castration-sensitive prostate cancer (mCSPC). Early declines in prostate-specific antigen (PSA), particularly achievement of a PSA90 response (a ≥90% reduction from baseline level), serve as important markers of treatment efficacy. This study assessed the proportion of patients with mCSPC and a detectable baseline PSA level (i.e., >0.2 ng/mL) who achieved a PSA90 response by 6 months after initiating apalutamide or abiraterone acetate.

**Methods:** A retrospective longitudinal cohort design was used to compare PSA90 response by 6 months between apalutamide- and abiraterone acetate-initiated patients captured in linked electronic clinical data from community urology practices (PPS Analytics) and U.S. administrative claims from the Komodo Research Database (1/1/2016–6/30/2025). Patients were classified based on their first documented fill or paid claim for either ARPI on or after 09/17/2019, the Food and Drug Administration approval date of apalutamide for mCSPC. Eligible patients had ≥1 metastatic diagnosis, no evidence of castration-resistant disease before or on the index date (assessed from physician notes in the urology data and observed increases in PSA following medical or surgical castration), ≥12 months of pre-index clinical activity, and a detectable PSA level from the most recent measurement within 13 weeks prior to or on the index date. Follow-up spanned from the index date to the earliest of ARPI discontinuation (≥90-day gap), initiation of another ARPI, radiopharmaceutical use, and end of PPS clinical activity. Baseline characteristics were balanced using inverse probability of treatment weighting, and weighted Cox proportional hazards models were used to compare PSA90 achievement between both cohorts.

**Results:** The analysis included 1,567 apalutamide patients (weighted characteristics: median age 74 years, 64% White, 79% enrolled in Medicare, median baseline PSA 6.2 ng/ml) and 1,116 abiraterone acetate patients (weighted characteristics: median age 73 years, 64% White, 78% enrolled in Medicare, median baseline PSA 6.6 ng/ml). Bone metastases were the most common metastatic site (58% in each cohort), visceral metastases occurred in 17% of patients in both groups, and 28% of apalutamide patients and 29% of abiraterone acetate patients had metastases in multiple locations. The median time between first metastatic diagnosis and ARPI initiation was 1.6 months in both treatment cohorts. By 6 months, 74.6% of apalutamide patients and 61.0% of abiraterone acetate patients achieved a PSA90 response (hazard ratio [HR]: 1.36; 95% confidence interval [CI]: 1.22, 1.52; $p < 0.001$). Results were consistent when assessing PSA90 using all follow-up (HR: 1.37; 95% CI: 1.23, 1.52). Median time to PSA90 was numerically shorter in apalutamide patients (2.8 months), relative to abiraterone acetate patients (3.6 months).

**Conclusion:** In this real-world cohort study of patients with mCSPC, initiating apalutamide was associated with a significantly higher rate of achieving a deep PSA90 response by 6 months relative to patients initiated on abiraterone acetate. Given the established relationship between profound early PSA declines and improved long-term outcomes, these findings underscore the potential clinical relevance of choosing apalutamide for achieving rapid, meaningful disease control.


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