ERLEADA® (apalutamide)
Poster Summary: Lowentritt et al 2024 – Real-World OS Comparison with Abiraterone Acetate in Patients with mCSPC

REAL-WORLD STUDY

Lowentritt et al (2024)[1] conducted a real-world study to compare overall survival (OS) by 24 months in androgen receptor pathway inhibitor (ARPI)-naïve patients with metastatic castration-sensitive prostate cancer (mCSPC) who were newly initiated on ARPIs, ERLEADA (n=1879) or abiraterone acetate (n=2073).

Study Design/Methods

- Real-world, retrospective, head-to-head, longitudinal study
- Clinical data from Precision Point Specialty (PPS) Analytics collected as part of routine clinical care from community-based urology practices in the United States (US) were linked with administrative claims data from the Komodo Research Database (KRD) obtained from September 17, 2018 to December 31, 2023. Patients were assigned to mutually exclusive treatment cohorts based on the first dispensation or paid pharmacy claim (index date) for ERLEADA or abiraterone acetate.
- ARPI-naïve patients with mCSPC were required to have a diagnosis code or clinical indicator for bone, nodal, or visceral metastasis without castration resistance prior to or on the index date. Concomitant use of androgen deprivation therapy (ADT) was not required for inclusion in either cohort; concomitant use of prednisone was not required for inclusion in the abiraterone acetate cohort.
- Baseline patient characteristics were evaluated 12 months preceding the index date.
- Treatment patterns were assessed from the index date up to 24 months.
- Inverse probability of treatment weighting (IPTW) based on propensity score was used to account for differences in baseline characteristics between the ERLEADA and abiraterone acetate cohorts.
    - Each patient was attributed an inverse probability of treatment weight, defined as 1/(propensity score) for the ERLEADA cohort and 1/(1-propensity score) for the abiraterone acetate cohort.
- A weighted Kaplan-Meier analysis was used to assess the proportion of patients surviving by 24 months postindex and weighted Cox proportional hazards models were used to evaluate the causal relationship between the index treatment and OS.
    - HR <1 indicates a lower rate of death for the ERLEADA cohort compared with the abiraterone acetate cohort.
- **Primary outcome:** Proportion of patients who survived by 24 months postindex ARPI initiation
- This study was not designed to assess differences in safety between cohorts.

Results

Patient Characteristics

- Concomitant ADT use was observed in 76.8% of patients in the ERLEADA weighted cohort and 74.0% in the abiraterone acetate weighted cohort.
- Baseline patient characteristics were well-balanced between weighted cohorts, with standardized differences <10%.
- Patient demographics and baseline characteristics in the weighted population are included in Table: Demographics and Baseline Disease Characteristics.

Demographics and Baseline Disease Characteristics[1]

Characteristic	Weighted Population[a]		
	ERLEADA (n=1879)	Abiraterone Acetate (n=2073)	Standardized difference, %
Mean age, years (SD)	72.1 (9.3)	71.9 (9.1)	2.5
Race, n (%)			
White	1159 (61.7)	1295 (62.5)	1.6
Black or African American	359 (19.1)	374 (18.0)	2.8
Hispanic or Latino	141 (7.5)	152 (7.3)	0.6
Other	85 (4.5)	100 (4.8)	1.3
Unknown	134 (7.1)	152 (7.3)	0.7
Geographic region, n (%)			
South	900 (47.9)	923 (44.5)	6.8
Midwest	515 (27.4)	602 (29.0)	3.6
Northeast	247 (13.1)	296 (14.3)	3.3
West	217 (11.5)	253 (12.2)	2.0
Index year, n (%)			
2019-2020	414 (22.0)	473 (22.8)	1.8
2021	444 (23.6)	484 (23.3)	0.8
2022	514 (27.4)	555 (26.8)	1.3
2023	506 (27.0)	562 (27.1)	0.4
Mean time between metastasis and index date, months (SD)	9.7 (17.6)	10.2 (17.1)	2.5
Mean time between PC diagnosis and index date, months (SD)	37.4 (45.5)	35.5 (47.7)	0.3
Metastasis type,[b] n (%)			
Bone	1249 (66.5)	1373 (66.2)	0.6
Nodal	994 (52.9)	1097 (52.9)	0.1
Visceral	396 (21.1)	477 (23.0)	4.7
Metastasis in multiple sites	477 (25.4)	492 (23.7)	3.9
Mean Quan-CCI (SD)	8.5 (3.0)	8.5 (2.9)	0.7
De novo PC,[c] n (%)	1100 (58.5)	1223 (59.0)	1.0
Concurrent use of ADT with index ARPI,[d] n (%)	1443 (76.8)	1535 (74.0)	6.4
Mean duration of ADT episode overlapping with index date, months (SD)	4.5 (8.0)	5.0 (8.3)	6.4
Prior use of first-generation ARPI,[e] n (%)	343 (18.2)	396 (19.1)	2.2
Prior use of chemotherapy,[f] n (%)	51 (2.7)	72 (3.5)	4.6
Most recent PSA level, ng/mL, n (%)			
≤0.2	288 (15.3)	298 (14.4)	2.7
>0.2 to ≤2	286 (15.2)	296 (14.3)	2.7
>2 to ≤5	186 (9.9)	194 (9.3)	1.9
>5 to ≤10	168 (9.0)	172 (8.3)	2.3
>10	533 (28.4)	577 (27.8)	1.3
Unknown	417 (22.2)	537 (25.9)	8.7
Initial Gleason score,[g] n (%)			
≤6	94 (5.0)	97 (4.7)	1.6
7	355 (18.9)	383 (18.5)	1.1
8	276 (14.7)	311 (15.0)	0.9
9	408 (21.7)	446 (21.5)	0.6
10	60 (3.2)	65 (3.2)	0.3
Unknown	685 (36.5)	771 (37.2)	1.5

Characteristic	Weighted Population[a]		
	ERLEADA (n=1879)	Abiraterone Acetate (n=2073)	Standardized difference, %

Abbreviations: ADT, androgen deprivation therapy; ARPI, androgen receptor pathway inhibitor; CCI, Charlson Comorbidity Index; PC, prostate cancer; PSA, prostate-specific antigen; SD, standard deviation.
[a]The number of patients reported in this weighted population represents the sum of weights for the corresponding nonweighted patients, rounded to the nearest integer. The proportions displayed were calculated before rounding and may be slightly different than if they were calculated based on rounded numbers.
[b]Types of metastases were defined at any time prior to (and including) the index date. The types of metastases were not mutually exclusive.
[c]*De novo* PC was defined as ≤180 days between the first PC diagnosis and date of metastasis.
[d]Concurrent ADT use was defined as an episode of continuous ADT use overlapping with the index date (using a 60-day gap to define discontinuation).
[e]Prior use of first-generation ARPI was defined as any prescription for bicalutamide, nilutamide, or flutamide in the 12 months preceding the index date.
[f]Prior chemotherapy use was defined as administration at any time prior to (and excluding) the index date.
[g]The Gleason score was evaluated at any time prior to and including the index date.

OS

24 Months Postindex

- Patients initiated on ERLEADA had a statistically significant 26% reduction in the risk of death when compared with patients initiated on abiraterone acetate (hazard ratio [HR], 0.74; 95% confidence interval [CI], 0.59-0.93; *P*=0.010).
- The proportion of patients surviving at 24 months postindex was 88.7% in the ERLEADA cohort and 85.8% in the abiraterone acetate cohort.

48 Months Postindex

- When evaluating OS using all available follow-up at 48 months postindex, results were consistent with OS at 24 months postindex (HR, 0.72; 95% CI, 0.59-0.88; nominal *P*<0.001). This endpoint was not adjusted for multiple comparisons. Therefore, the p-value displayed is nominal, and statistical significance has not been established.
- The proportion of patients surviving at 24 months postindex was 77.3% in the ERLEADA cohort and 69.4% in the abiraterone acetate cohort.

Treatment Patterns

- The mean (median) follow-up duration was 16.8 (19.5) months for the ERLEADA cohort and 16.3 (19.0) months for the abiraterone acetate cohort.
- The mean (median) duration of continuous index ARPI use (using a 90-day gap in treatment to define discontinuation) was 9.3 (6.6) months for the ERLEADA cohort and 10.7 (8.9) months for the abiraterone acetate cohort.

Safety results were not reported.

REFERENCES

1. Lowentritt B, Bilen MA, Khilfeh I, et al. Overall survival in patients with metastatic castration sensitive prostate cancer treated with apalutamide versus abiraterone acetate – a head-to-head analysis of real-world patients in the United States. Poster presented at: European Conference of Oncology Pharmacy (ECOP); October 2-4, 2024; Lisbon, Portugal.