ZYTIGA® (abiraterone acetate)
Comparison of ZYTIGA to Docetaxel in Metastatic Castration-Sensitive Prostate Cancer

SUMMARY

- PEACE-1 is an ongoing, phase 3, randomized study evaluating the efficacy and safety of ZYTIGA plus prednisone in addition to standard of care (SOC; androgen deprivation therapy [ADT] or ADT plus docetaxel) with or without radiotherapy in men with de novo metastatic castration-sensitive prostate cancer (mCSPC; N=1172). The coprimary endpoints were radiographic progression-free survival (rPFS) and overall survival (OS).[1]
    - Among patients who received ZYTIGA plus prednisone with ADT and docetaxel, a statistically significant improvement in rPFS was observed compared to patients who received ADT plus docetaxel without ZYTIGA (median 4.5 years vs 2.0 years; HR, 0.50; 99.9% CI, 0.34-0.71; *P*<0.0001). OS was also improved in these patients (median not reached [NR] vs 4.4 years; HR, 0.75; 95.1% CI, 0.59-0.95; *P*=0.017).
    - Grade 3 or worse adverse events (AEs) reported in >5% of patients in the ZYTIGA with ADT and docetaxel arm included hypertension, neutropenia, and hepatotoxicity. A summary of AEs is provided in Table: Adverse Events in the Safety Population.
    - A post-hoc analysis was conducted to evaluate the efficacy and safety of ZYTIGA plus prednisone in older men (≥70 years) vs younger men (<70 years) with de novo mCSPC. In older men vs younger men, the benefit of ZYTIGA plus prednisone on rPFS (HR, 0.65; 95% CI, 0.42-1.01 vs HR, 0.49; 95% CI, 0.35-0.69) and OS (HR, 0.95; 95% CI, 0.72-1.25 vs HR, 0.73; 95% CI, 0.58-0.92) tended to decrease with age. For patients receiving ZYTIGA plus prednisone plus SOC consisting of ADT plus docetaxel, rPFS benefits were similar.[2]
    - An analysis of the association of PSA value at 8 months after ADT initiation to rPFS and OS is summarized below.[3]
- STAMPEDE is an ongoing, randomized, multi-arm, multi-stage study assessing whether the addition of further therapy to SOC improves OS in patients initiating long-term ADT for the first time for locally advanced or metastatic prostate cancer.[4]
    - In a subset analysis comparing patients who received either docetaxel with prednisolone/prednisone plus SOC (DocP) or ZYTIGA with prednisolone/prednisone (AAP) plus SOC (N=566), the HRs for OS and failure-free survival (FFS), respectively, were 1.16 (95% CI, 0.82-1.65; *P*=0.404) and 0.51 (95% CI, 0.39-0.67; *P*<0.001). A total of 48% and 50% of patients in the AAP plus SOC and DocP plus SOC groups, respectively, experienced grade 3-5 AE.[5]
    - Results from an evaluation of nodal burden as a prognostic biomarker for OS in patients receiving DocP plus SOC and AAP plus SOC have been reported.[6]

CLINICAL DATA

PEACE-1 Study

Fizazi et al (2022)[1] reported results from an ongoing phase 3 study evaluating the efficacy and safety of ZYTIGA plus prednisone with or without radiotherapy and SOC (ADT alone or with docetaxel) in men with de novo mCSPC (N=1172; NCT01957436).

Study Design/Methods

- Phase 3, randomized, open-label, active-controlled study with a 2×2 factorial design
- Patients were randomized 1:1:1:1 to receive SOC (ADT alone or with docetaxel; n=296), SOC plus radiotherapy (n=293), ZYTIGA with prednisone plus SOC (n=292), or ZYTIGA with prednisone plus SOC and radiotherapy (n=291). ZYTIGA with prednisone was administered until disease progression to castration resistance, withdrawal of consent, unacceptable toxicity, or death.

- Patients assigned to receive ZYTIGA received 1000 mg of ZYTIGA orally (PO) once daily (QD) with prednisone 5 mg twice daily (BID) starting within 6 weeks after ADT initiation.
- Patients assigned to receive docetaxel as a part of SOC received 6 cycles of 75 mg/m^2 docetaxel intravenously (IV; maximum dose of 150 mg/cycle) once every 3 weeks starting within 14 days after randomization and ≥6 weeks of ADT initiation.
- Patients assigned to receive radiotherapy received a dose of 74 gray (Gy) in 37 fractions administered over 7-8 weeks starting within 3-8 weeks of docetaxel completion.
- In all patients, ADT was continuously maintained by either a gonadotropin-releasing hormone agonist or antagonist or bilateral orchiectomy.

- **Coprimary endpoints:** rPFS and OS
- **Select secondary endpoints:** CRPC-free survival, prostate cancer-specific survival, prostate-specific antigen (PSA) response rate, prognostic study of serum PSA measured 6-8 months after initiation of systemic therapy, event rate per 100 patient-years of treatment analysis, and toxicity

Results

Patient Characteristics

- SOC was ADT alone in 462 patients and ADT plus docetaxel in 710 patients.
- The results pertaining only to the population that received SOC with ADT plus docetaxel are summarized in this section.
- Select baseline characteristics of patients who received ADT plus docetaxel as SOC are summarized in Table: Select Baseline Patient and Disease Characteristics.

Select Baseline Patient and Disease Characteristics[1]

Characteristic	ADT Plus Docetaxel Population (n=710)[a]	
	SOC Plus ZYTIGA (With or Without Radiotherapy; n=355)	SOC Without ZYTIGA (With or Without Radiotherapy; n=355)
Assigned to receive radiotherapy, n (%)	178 (50)	177 (50)
Median age, years (IQR)	66 (60-70)	66 (59-70)
ECOG performance status, n (%)		
0	250 (70)	246 (69)
1-2	105 (30)	109 (31)
Time from diagnosis, months		
Median (IQR)	2.2 (1.6-3.0)	2.2 (1.4-2.9)
Metastatic localization, n (%)		
Bone[b]	287 (81)	279 (79)
Lymph node only	27 (8)	29 (8)
Visceral[c]	41 (12)	47 (13)
Metastatic burden[d], n (%)		
High burden	224 (63)	232 (65)
Low burden	131 (37)	123 (35)
Gleason score, n (%)		
≤7	79 (23)	71 (20)

8-10	270 (77)	276 (80)
Missing data	6 (2)	8 (2)
PSA at randomization, ng/mL		
Median (IQR)	14 (2-59)	12 (3-60)

Abbreviations: ADT, androgen deprivation therapy; ECOG, Eastern Cooperative Oncology Group; IQR, interquartile range; PSA, prostate-specific antigen; SOC, standard of care.
[a]The median number of docetaxel cycles was 6 (IQR, 6-6) in both groups.
[b]Without visceral metastases.
[c]With or without lymph node and bone metastases.
[d]The metastatic burden was classified as a high burden characterized by the presence of ≥4 bone metastases with ≥1 outside the vertebral bodies or pelvis, visceral metastases, or both; all other assessable situations were classified as low burden.

Efficacy

- In the ADT plus docetaxel population:
  - The median follow-up duration for rPFS and OS were 3.0 years (interquartile range [IQR], 2.1-3.8) and 3.8 years (IQR, 2.9-4.5), respectively.
  - No interaction between ZYTIGA and radiotherapy was found for rPFS (*P*=0.94), OS (*P*=0.85), CRPC-free survival (*P*=0.75), or prostate cancer-specific survival (*P*=0.98).
  - The addition of ZYTIGA to SOC decreased the number of radiographic progression events or deaths from 211 to 139, increased the median rPFS from 2.03 years (IQR, 1.09-NR) to 4.46 years (IQR, 1.90-NR), and reduced the relative risk of radiographic progression or death in patients by 50% compared with those who did not receive ZYTIGA (adjusted HR for rPFS, 0.50; 99.9% CI, 0.34-0.71; *P*<0.0001).
  - The addition of ZYTIGA to SOC reduced the number of deaths from 151 to 121, increased the median OS from 4.43 years (IQR, 2.47-NR) to NR, and reduced the relative risk of death from any cause by 25% (adjusted HR for OS, 0.75; 95.1% CI, 0.59-0.95; *P*=0.017).
  - The addition of ZYTIGA to SOC reduced the relative risk of radiographic progression or death by 42% and 53% in patients with low- and high-volume metastatic burden, respectively (low-volume burden: median rPFS, NR vs 2.7 years; adjusted HR, 0.58 [99.9% CI, 0.29-1.15; *P*=0.0061]; high-volume burden: median rPFS, 4.1 years vs 1.6 years; adjusted HR, 0.47 [99.9% CI, 0.30-0.72; *P*<0.0001]).
  - The addition of ZYTIGA to SOC increased OS in patients with high-volume metastatic burden (high-volume burden: median OS, 5.14 years vs 3.47 years; adjusted HR, 0.72 [95.1% CI, 0.55-0.95; *P*=0.019]). Data for OS in patients with low metastatic burden were not mature at the final planned analysis.
- Efficacy outcomes in the ADT plus docetaxel population are provided in Table: Primary and Secondary Outcomes in the ADT plus Docetaxel Population.

Primary and Secondary Outcomes in the ADT Plus Docetaxel Population[1]

	ADT Plus Docetaxel Plus ZYTIGA Groups (n=355)	ADT Plus Docetaxel Without ZYTIGA Groups (n=355)	HR	*P* Value
Primary outcomes				
Median OS, years	NR	4.4	0.75 (95.1% CI, 0.59-0.95)	0.017
Median rPFS, years	4.5	2.0	0.50 (99.9% CI, 0.34-0.71)	<0.0001
Secondary outcomes				

Median CRPC-free survival, years	3.2	1.4	0.38 (95% CI, 0.31-0.47)	<0.0001
Median prostate cancer-specific survival, years	NR	4.7	0.69 (95% CI, 0.53-0.90)	0.0062

Abbreviations: ADT, androgen deprivation therapy; CI, confidence interval; CRPC, castration-resistant prostate cancer; HR, hazard ratio; NR, not reached; OS, overall survival; pts, patients, rPFS, radiographic progression-free survival.

Safety

- AEs are summarized in Table: Adverse Events in the Safety Population.
- Addition of docetaxel to ZYTIGA did not increase the incidence of severe or fatal AEs.
  - In the ADT plus docetaxel population, 49 severe AEs occurred per 100 patient-years in patients who received ZYTIGA vs 55 per 100 patient-years in those who did not receive ZYTIGA.
- In the ADT plus docetaxel population, the incidence of severe AEs reported in ≥5% of patients was similar between patients who received ZYTIGA and those who did not receive ZYTIGA, except for hypertension (22% and 13%, respectively) and hepatotoxicity with increased aminotransferases (6% and 1%, respectively).
- Treatment with ZYTIGA was discontinued in 138 of 226 (61%) patients receiving ADT plus docetaxel and 183 of 347 (53%) patients receiving ADT without docetaxel, including 29 of 138 (21%) and 32 of 183 (17%) patients due to toxicity, respectively.
- The median duration of treatment with ZYTIGA before discontinuation was 34.1 months (95% CI, 30.0-43.5) in the ADT plus docetaxel population and 33.2 months (95% CI, 25.5-43.2) in the ADT without docetaxel population.

Adverse Events in the Safety Population[1]

Event, n (%)	ADT With Docetaxel Population		ADT Without Docetaxel Population	
	ADT Plus Docetaxel Plus ZYTIGA (With or Without Radiotherapy; n=347)	ADT Plus Docetaxel Without ZYTIGA (With or Without Radiotherapy; n=350)	ADT Plus ZYTIGA (With or Without Radiotherapy; n=226)	ADT Without ZYTIGA (With or Without Radiotherapy; n=237)
Any AEs	346 (100)	349 (100)	226 (100)	233 (99)
Severe (grade ≥3) AEs	217 (63)	181 (52)	149 (66)	97 (41)
Fatal (grade 5) AEs	7 (2)	3 (1)	8 (4)	5 (2)
Frequent (≥5%) severe AEs				
Hypertension	76 (22)	45 (13)	66 (29)	38 (16)
Neutropenia	34 (10)	32 (9)	0	0
Hepatotoxicity	20 (6)	2 (1)	14 (6)	3 (1)
Febrile neutropenia	18 (5)	19 (5)	2 (1)	1 (<1)
Gamma-glutamyl transferase increase	17 (5)	14 (4)	6 (3)	4 (2)
Erectile dysfunction	7 (2)	5 (1)	12 (5)	13 (5)
Blood alkaline phosphatase increase	15 (4)	12 (3)	6 (3)	13 (5)

Other severe AEs				
Fatigue	10 (3)	15 (4)	3 (1)	0
Peripheral neuropathy	4 (1)	6 (2)	1 (<1)	0
Abbreviations: ADT, androgen deprivation therapy; AE, adverse event.				

Post-Hoc Analysis

A post hoc analysis was conducted to evaluate the efficacy and safety of ZYTIGA plus prednisone in older men (≥70 years) vs younger men (<70 years) with de novo mCSPC. A total of 431 older men (37%) and 741 younger men (63%) were randomized. In older men vs younger men, ECOG performance status 1-2 was 36% vs 26%, docetaxel use as part of SOC was 51% vs 66%, baseline hypertension was 56.5% vs 38.2%, and baseline diabetes mellitus type 2 was 15.5% vs 11%, respectively.[2]

- In older men vs younger men, the benefit of ZYTIGA plus prednisone on rPFS (HR, 0.65; 95% CI, 0.42-1.01 vs HR, 0.49; 95% CI, 0.35-0.69) and OS (HR, 0.95; 95% CI, 0.72-1.25 vs HR, 0.73; 95% CI, 0.58-0.92) tended to decrease with age.
- In men that received ADT with docetaxel as part of SOC, the benefit of ZYTIGA plus prednisone on rPFS (HR, 0.55; 95% CI, 0.29-1.04 vs HR, 0.5; 95% CI, 0.33-0.78) was comparable in older men vs younger men and for OS was (HR, 0.80; 95% CI, 0.53-1.2 vs HR, 0.71; 95% CI, 0.52-0.95), respectively.
- Older men had a shorter median time to discontinuation of ZYTIGA plus prednisone compared to younger men (30.0 months [95% CI, 22.1-35.4] vs 41.4 [95% CI, 31.5-54.0]) independent of docetaxel use and discontinuation was more frequently due to AEs or death for older men compared to younger men. Severe AEs (grade 3-5) were more frequent in older men receiving ZYTIGA plus prednisone compared to younger men (69% vs 61%, respectively), while AE rates in patients not receiving ZYTIGA plus prednisone were similar between older men and younger men (48% vs 47%, respectively).

Preplanned Analysis

A preplanned analysis was conducted to analyze the association of PSA value at 8 months after ADT initiation to rPFS and OS in patients with mCSPC receiving SOC +/- ZYTIGA with prednisone in the PEACE-1 study. An 8-month PSA value was required for inclusion in the analysis (n=931). The median follow-up was 4.4 years (95% CI, 4.3-4.5). ADT plus docetaxel was SOC in 62% of patients, and 56% of patients had high volume disease.[3] Efficacy results are described below in Table: PSA and Efficacy Outcomes.

PSA and Efficacy Outcomes[3]

Years (95% CI)	ADT +/- Docetaxel	ADT Plus Docetaxel	ADT With ZYTIGA +/- Docetaxel	ADT With ZYTIGA Plus Docetaxel
Median rPFS	n=439	n=286	n=441	n=268
PSA <0.2 ng/mL	4.0 (3.6-NR)	3.7 (2.1-NR)	NR (4.7-NR)	4.7 (4.5-NR)
PSA >0.2 ng/mL[a]	1.4 (1.2-1.7)	1.3 (1.1-1.5)	2.2 (1.6-2.9)	2.5 (1.6-3.4)
PSA <4 ng/mL	2.5 (2.0-3.1)	2.1 (1.7-3.0)	5.4 (4.1-NR)	4.5 (3.5-NR)
PSA >4 ng/mL[a]	0.7 (0.5-1.0)	0.5 (0.4-1.0)	0.7 (0.3-1.1)	0.7 (0.3-1.2)
Median OS	n=471	n=297	n=458	n=276
PSA <0.2 ng/mL	NR (4.8-NR)	NR (4.0-NR)	NR (5.7-NR)	NR (4.7-NR)
PSA >0.2 ng/mL[a]	3.5 (3.1-4.1)	3.5 (2.8-4.0)[b]	3.4 (2.8-3.9)	3.6 (2.9-NR)
PSA <4 ng/mL	5.9 (4.7-NR)	4.5 (4.0-NR)	6.1 (5.2-NR)	NR (4.7-NR)

PSA >4 ng/mL[a]	2.1 (1.7-2.4)	2.1 (1.5-2.5)	1.5 (0.9-1.9)	1.6 (0.9-2.4)

Abbreviations: ADT, androgen deprivation therapy; CI, confidence interval; NR, not reached; OS, overall survival; PSA, prostate-specific antigen; rPFS, radiographic progression-free survival.
[a]*P*<0.0001.
[b]*P*=0.0007.

STAMPEDE STUDY

The STAMPEDE study is an ongoing, randomized, multi-arm, multi-stage study evaluating whether the addition of further therapy to SOC improves OS in patients initiating long-term ADT for the first time for locally advanced or metastatic prostate cancer (NCT00268476).[4]

Sydes et al (2018)[5] evaluated the survival outcomes in a subset of patients from the STAMPEDE study who received either docetaxel plus SOC or ZYTIGA plus SOC (N=566).

Study Design/Methods

- Patients were contemporaneously randomized 2:1:2 to receive SOC, DocP plus SOC (n=189), or AAP plus SOC (n=377).
  - SOC: long-term ADT or 2+ years ADT (plus radiotherapy for some non-metastatic disease [M0])
  - DocP: docetaxel 75 mg/m^2 every 3 weeks for 6 cycles plus prednisone/prednisolone 10 mg QD
  - AAP: ZYTIGA 1000 mg plus prednisolone/prednisone 5 mg PO QD
- The duration of treatment with AAP was capped after 2 years in M0 patients having radical radiotherapy.
- The primary outcome measure (OM) was OS, and the intermediate primary OM was FFS (defined as time from randomization to rising PSA, new disease or progression of distant metastases, lymph nodes, or local disease, or death from prostate cancer).

Results

Patient Characteristics

- Treatment groups were well balanced.
  - M1: n=342 (60%)
  - Gleason 8-10: n=429 (76%)
  - World Health Organization (WHO) performance status 0: n=449 (79%)
- Median age was 66 years, and median PSA level was 56 ng/mL.

Efficacy

- At a median follow-up of 48 months, 44/189 deaths were reported in the DocP plus SOC group and 105/377 in the AAP plus SOC group; see Table: Efficacy Outcomes.
- Among the 149 deaths reported, 126 were attributed to prostate cancer (baseline metastasis status: M0, n/N=10/22; M1, n/N=116/127) and 23 were attributed to other causes; see Table: Deaths From Prostate Cancer and Other Causes.
- No heterogeneity was observed in the treatment effect by baseline metastases status for OS, prostate cancer-specific survival, non-prostate cancer-specific survival, FFS, progression-free survival (PFS), metastatic PFS, and skeletal-related events.

Efficacy Outcomes[5]

Outcome Measure	Patient Group	Events/Patient		HR[a] (95% CI)	*P* Value	Interaction by Metastases *P* Value
		DocP With SOC	AAP With SOC			
OS	All	44/189	105/377	1.16 (0.82-1.65)	0.404	0.691
	M0	6/74	16/150	1.51 (0.58-3.93)	0.395	
	M1	38/115	89/227	1.13 (0.77-1.66)	0.528	
FFS[b]	All	97/189	122/377	0.51 (0.39-0.67)	<0.001	0.169
	M0	18/74	13/150	0.34 (0.16-0.69)	0.003	
	M1	79/115	109/227	0.56 (0.42-0.75)	<0.001	
PFS[b]	All	72/189	103/377	0.65 (0.48-0.88)	0.005	0.323
	M0	10/74	9/150	0.42 (0.17-1.05)	0.064	
	M1	62/115	94/227	0.69 (0.50-0.95)	0.023	
Metastatic PFS[c]	All	71/189	118/377	0.77 (0.57-1.03)	0.079	0.744
	M0	10/74	18/150	0.91 (0.42-2.01)	0.824	
	M1	61/115	100/227	0.76 (0.55-1.04)	0.085	
Freedom from symptomatic skeletal events	All	36/189	63/377	0.83 (0.55-1.25)	0.375	0.648
	M0	2/74	5/150	1.28 (0.24-6.67)	0.771	
	M1	34/115	58/227	0.82 (0.53-1.25)	0.351	

Abbreviations: AAP, ZYTIGA with prednisolone/prednisone; CI, confidence interval; DocP, docetaxel with prednisolone/prednisone; FFS, failure-free survival; HR, hazard ratio; OS, overall survival; PFS, progression-free survival; SOC, standard of care.
[a]From the Cox proportional hazards model, adjusted for stratification factors at randomization (except hospital and choice of hormone therapy) and stratified by time period.
[b]Includes death from prostate cancer.
[c]Includes death from any cause.

Deaths From Prostate Cancer and Other Causes[5]

Outcome Measure	Patient Group	Events/Patient		Sub-HR[a] (95% CI)	*P* Value	Interaction by Metastases *P* Value
		DocP With SOC	AAP With SOC			
Death from prostate cancer[b]	All	40/189	86/377	1.02 (0.70-1.49)	0.916	0.620
	M0	4/74	6/150	0.82 (0.24-2.81)	0.751	
	M1	36/115	80/227	1.05 (0.71-1.56)	0.807	
Death from other causes[c]	All	4/189	19/377	2.33 (0.77-6.99)	0.131	0.771
	M0	2/74	10/150	3.00 (0.66-13.66)	0.155	
	M1	2/115	9/227	1.91 (0.43-8.41)	0.393	

Abbreviations: AAP, ZYTIGA with prednisolone/prednisone; CI, confidence interval; DocP, docetaxel with prednisolone/prednisone; HR, hazard ratio; SOC, standard of care.
[a]From competing risks regression model, adjusted for stratification factors at randomization (except hospital and choice of hormone therapy) and time period, and treating causes of death other than the focus as a competing event.
[b]Cause attributed to central death review; prostate cancer death as an event, other causes of death as a competing event.
[c]Cause attributed to central death review; other causes of death as an event, prostate cancer as a competing event.

Safety

- A total of 48% and 50% of patients in the AAP with SOC and DocP with SOC groups, respectively, experienced a grade 3-5 AE; see Table: Summary of Adverse Events.

Summary of Adverse Events[5]

	DocP with SOC (n=189)	AAP with SOC (n=377)
Number of patients included in the analysis (safety population)[a]	172	373
Patients with an AE, n (%)		
Grade 1-5 AE	172 (100)	370 (99)
Grade 3-5 AE	86 (50)	180 (48)
Grade 3-5 AEs, n (%)		
Endocrine disorder	15 (9)	49 (13)
Febrile neutropenia	29 (17)	3 (1)
Neutropenia	22 (13)	4 (1)
General disorder	18 (10)	21 (6)
Fatigue	7 (4)	8 (2)
Edema	1 (1)	2 (1)
Musculoskeletal disorder	9 (5)	33 (9)
Cardiovascular disorder	6 (3)	32 (9)
Hypertension	0 (0)	12 (3)
Myocardial infarction	2 (1)	4 (1)
Cardiac dysrhythmia	1 (1)	5 (1)
Gastrointestinal disorder	9 (5)	28 (8)
Hepatic disorder	1 (1)	32 (9)
Increased AST	0 (0)	6 (2)
Increased ALT	1 (1)	23 (6)
Respiratory disorder	12 (7)	11 (3)
Dyspnea	4 (2)	1 (1)
Renal disorder	5 (3)	20 (5)
Laboratory abnormalities	9 (5)	11 (3)
Hypokalemia	0 (0)	3 (1)

Abbreviations: AE, adverse event; AAP, ZYTIGA with prednisolone/prednisone; ALT, alanine aminotransferase; AST, aspartate aminotransferase; DocP, docetaxel with prednisolone/prednisone; SOC, standard of care.
[a]The safety population includes patients who started their allocated treatment.

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) was conducted on 27 April 2023. Summarized in this response are relevant data from phase 3 and prospective clinical studies in patients with mCSPC. Retrospective, real-world, patient-reported outcomes, systematic reviews, network meta-analyses, and cost analyses were excluded.

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