

# ZYTIGA® (abiraterone acetate) ZYTIGA - LATITUDE Study

## SUMMARY

A summary of the ZYTIGA - LATITUDE study is provided as an interactive PDF (iPDF) that can be accessed by clicking the following link:

- [ZYTIGA - LATITUDE Study](#)
- Minimum requirement to access interactive content: Adobe Acrobat Reader
- The executive summary infographic of the iPDF content is provided below

## ZYTIGA® (abiraterone acetate) LATITUDE Study

Executive Summary	Study Design and Endpoints	Baseline Characteristics	Efficacy Results	Safety Results	Additional Analyses	Abbreviations and References
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### Study Overview

LATITUDE (NCT01715285) was a phase 3, randomized, double-blind, placebo-controlled, multicenter study of ZYTIGA plus daily prednisone with ADT vs placebos with ADT in 1199 patients with newly diagnosed, metastatic high-risk CSPC.<sup>1</sup>

### Key Efficacy Outcomes

- OS (coprimary endpoint) was significantly improved in the ZYTIGA plus prednisone with ADT group vs the placebos with ADT group (median, NR vs 34.7 months, respectively; HR, 0.62; 95% CI, 0.51-0.76;  $P < 0.001$ ).<sup>1</sup>
- rPFS (coprimary endpoint) was significantly improved in the ZYTIGA plus prednisone with ADT group vs the placebos with ADT group (median, 33.0 vs 14.8 months, respectively; HR, 0.47; 95% CI, 0.39-0.55;  $P < 0.001$ ).<sup>1</sup>
- Significant improvements in all secondary endpoints were also observed in the ZYTIGA plus prednisone with ADT group.<sup>1</sup>
- The final survival analysis was conducted after a median follow-up of 51.8 months.<sup>2</sup>
  - ZYTIGA plus prednisone with ADT continued to show significant OS improvement vs placebos with ADT, along with significant improvements in secondary endpoints.
  - Median OS was 53.3 months vs 36.5 months in the ZYTIGA plus prednisone with ADT group vs the placebos with ADT group, respectively (HR, 0.66; 95% CI, 0.56-0.78;  $P < 0.0001$ ).
  - An exploratory post hoc analysis demonstrated a significant improvement in both OS and rPFS for patients with high-volume disease and in rPFS for patients with low-volume disease who received ZYTIGA plus prednisone with ADT vs placebos with ADT.
- In an analysis of PROs and HRQoL, treatment with ZYTIGA plus prednisone with ADT resulted in significant improvements in time to worst pain intensity and pain interference progression, time to worst fatigue intensity and fatigue interference progression, and prolonged time to HRQoL deterioration.<sup>3</sup>

### Key Safety Outcomes

- The number of serious AEs and the frequency of AEs leading to treatment discontinuation were similar between groups.<sup>1</sup>
- Grade 3/4 events reported in >5% of patients were hypertension (20%/0% vs 10%/0.2%) and hypokalemia (10%/0.8% vs 1%/0.2%) in the ZYTIGA plus prednisone with ADT vs placebos with ADT groups, respectively.<sup>1</sup>
- Safety results from the final analysis were consistent with prior interim analyses.<sup>2</sup>

### Additional Analyses

- Additional analyses that evaluated PSA response, PSA progression, effect of switching treatment, effect of subsequent therapies, outcomes in visceral metastases, and effect of concomitant medications are described ahead.<sup>4-10</sup>
- Results from a post hoc analysis evaluating the prevalence and association of AR anomalies with time to OS and rPFS have been reported.<sup>11</sup>

ADT, androgen deprivation therapy; AR, androgen receptor; CI, confidence interval; CSPC, castration-sensitive prostate cancer; HR, hazard ratio; HRQoL, health-related quality of life; NR, not reached; OS, overall survival; PRO, patient-reported outcome; rPFS, radiographic progression-free survival.