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Long-term overall survival with abiraterone acetate plus prednisone in the PEACE-1 phase 3 trial for de novo metastatic castration-sensitive prostate cancer (mCSPC)

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Background

Recent trials demonstrated the benefit of systemic treatment intensification in mCSPC. However, long-term analyses are rare, especially for pharma industry trials. PEACE-1 (NCT01957436) is a 2x2 factorial phase 3 randomized trial that tested the addition of abiraterone acetate/prednisone (abiraterone) and/or prostate radiotherapy (RT) to standard of care (SOC) consisting of androgen deprivation therapy (ADT) with or without docetaxel.

Methods

1173 men (57% high-, 43% low-volume) with de novo mCSPC were randomized (1:1:1:1) to SOC, SOC+abiraterone, SOC+RT or SOC+abiraterone+RT. The initial analysis (median follow-up: 4.4 years [y]) showed abiraterone improved overall survival (OS) (HR: 0.82, 95% CI 0.69-0.98; p=0.030) (Fizazi K, Lancet 2022). Here we report long-term follow-up results.

Results

The median follow-up is 7.7 y. Abiraterone significantly improved survival (HR: 0.75 [95%CI: 0.65-0.87], p=0.0001) with median OS of 4.6 y (4.1-5.5) for SOC, 4.6 y (4.0-5.2) for SOC+RT, 5.7 y (4.8-6.6) for SOC+abiraterone, and 6.4 y (5.5-7.6) for SOC+RT+abiraterone, respectively. In the subgroup of 710 patients who received ADT+docetaxel as their SOC, adding abiraterone also improved survival (HR: 0.68 [0.56-0.82]), with a median OS of 4.4 y (4.0-4.9) for ADT+docetaxel (doublet) and 6.2 y (5.2-7.3) for ADT+docetaxel+abiraterone (triplet), resulting in 8-year survival rates of 27.1% (22.1-32.9) and 40.3% (34.3-46.6), respectively. The favorable effect of triplet therapy on OS was independent of metastatic extent (interaction test p= 0.56): median OS was 3.5 y (3.2-4.0) vs 4.6y (3.9-6.1) in patients with high-volume (HR: 0.68 [0.54; 0.85]) and 6.2 y (5.4-8.1) vs 7.8 y (6.4-NR) in patients with low-volume (HR: 0.74 [0.52-1.05]), for doublet versus triplet respectively. In patients with high-volume, 8-year OS rates were 20% (14.6-26.7) with doublet vs 38% (31.3-45.1) with triplet therapy.

Conclusions

Very long-term follow-up shows a major OS benefit of adding abiraterone to SOC for patients with mCSPC, irrespective of metastatic extent. Triplet therapy with ADT+docetaxel+abiraterone is associated with almost twice as many long-term survivors in some subgroups.

Clinical trial identification

NCT01957436.

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Legal entity responsible for the study

Unicancer.

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Disclosure

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