Efficacy and safety of enzalutamide in patients with metastatic castration-resistant prostate cancer previously treated with abiraterone acetate plus prednisone: A multicenter, single-arm, open-label study

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BACKGROUND
- Prostate cancer remains the most common form of cancer among men worldwide, and the third most common cause of cancer deaths in men worldwide.
- The management of castration-resistant prostate cancer (CRPC) has evolved over time with the introduction of novel systemic treatments.
- In response, this post-registration study (NCT02116582) was performed to evaluate the safety and efficacy of enzalutamide (ENZ) in patients with metastatic castration-resistant prostate cancer who had previously received treatment with abiraterone acetate plus prednisone.

METHODS
- Study design: This phase IV, multicenter, open-label, single-arm study of enzalutamide evaluated patients with CRPC following disease progression after at least 24 weeks of treatment with abiraterone acetate plus prednisone.
- Patients: Patients were eligible if they had histologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation, with progressive metastatic disease defined as PSA rise determined by a minimum of two rising PSA levels with an interval of at least 4 weeks and a minimum of 50% PSA decline was observed in patients with chemotherapy before abiraterone acetate plus prednisone.
- The study was not designed to provide definitive answers regarding treatment sequencing.
- This was a single-arm study design, which is not generally used as confirmation of efficacy. The study was designed to provide definitive answers regarding treatment sequencing, and further studies would be needed to assess the role of ENZ in this population.

RESULTS
- The safety profile was similar in both the chemotherapy-naive patients and patients who received chemotherapy prior to abiraterone acetate plus prednisone.
- The primary reason for treatment discontinuation in the overall population was disease progression (49.1%).
- The safety profile was similar in both the chemotherapy-naive patients and patients who received chemotherapy prior to abiraterone acetate plus prednisone.

ACKNOWLEDGMENTS
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REFERENCES

STUDY LIMITATIONS
- The safety profile was similar in both the chemotherapy-naive patients and patients who received chemotherapy prior to abiraterone acetate plus prednisone.
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CONCLUSIONS
- The study was not designed to provide definitive answers regarding treatment sequencing, and further studies would be needed to assess the role of ENZ in this population.
- The safety profile was similar in both the chemotherapy-naive patients and patients who received chemotherapy prior to abiraterone acetate plus prednisone.
- The study was not designed to provide definitive answers regarding treatment sequencing, and further studies would be needed to assess the role of ENZ in this population.

Overall survival
- A total of 105 (49.1%) patients had disease progression; 90 (42%) had symptomatic disease progression.
- The mean duration of overall survival was 9 months (95% CI 6.5, 9.6) in the overall population.
- The cut-off date is used as the last date of dosing for patients still on treatment by the cut-off date.
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Safety
- The safety profile was similar in both the chemotherapy-naive patients and patients who received chemotherapy prior to abiraterone acetate plus prednisone.
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Table 1

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Table 2

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<tr>
<td>PSA progression</td>
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<td>75</td>
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