Zytiga® (abiraterone acetate) – Expanded indication

- On February 7, 2018, the FDA announced the approval of Janssen's Zytiga (abiraterone acetate), in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer (CSPC).
    - Previously, Zytiga was approved in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC).
- Metastatic CSPC refers to prostate cancer that still responds to testosterone suppression therapy. Patients with newly diagnosed metastatic disease and high-risk disease characteristics tend to have a poorer prognosis.
- The efficacy of Zytiga in patients with metastatic high-risk CSPC was demonstrated in the placebo-controlled LATITUDE study that enrolled 1,199 patients. The major efficacy outcome was overall survival (OS).
    - In the Zytiga in combination with prednisone group, 28% of patients experienced death vs. 39% in the placebo group (median OS not estimable vs. 34.7 months, respectively; HR = 0.62 [95% CI: 0.51, 0.76]; $p < 0.0001$).
    - In addition, the major efficacy outcome was supported by a statistically significant delay in time to initiation of chemotherapy in the Zytiga arm vs. placebo arm. The median time to initiation of chemotherapy was not reached for patients on Zytiga with prednisone vs. 38.9 months for patients on placebo (HR = 0.44 [95% CI: 0.35, 0.56]; $p < 0.0001$).
- The recommended dosage of Zytiga for CSPC is 1,000 mg (two 500 mg tablets or four 250 mg tablets) orally once daily with prednisone 5 mg orally once daily.
    - Patients receiving Zytiga should also receive a gonadotropin-releasing hormone analog concurrently or should have had bilateral orchiectomy.
    - The recommended dose of Zytiga for CRPC is 1,000 mg once daily with prednisone 5 mg twice daily.