Lynparza® (olaparib) – New indication

- On May 20, 2020, AstraZeneca and Merck announced the FDA approval of Lynparza (olaparib), for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with Xtandi® (enzalutamide) or abiraterone.
    - Patients should be selected for therapy based on an FDA-approved companion diagnostic for Lynparza.
- Lynparza is also approved to treated ovarian cancer, breast cancer and pancreatic cancer.
- Prostate cancer is the second-most common cancer in men and five-year survival remains low for patients with mCRPC. HRR gene mutations occur in approximately 20 to 30% of patients with mCRPC.
- The new indication approval was based on the PROfound open-label study of 387 male patients with HRR gene-mutated mCRPC. Patients received Lynparza or investigator's choice of Xtandi or abiraterone. The major efficacy outcome of the study was radiological progression free survival (rPFS) in patients with *BRCA1*, *BRCA2*, or *ATM* mutations (Cohort A; n = 245).
    - The median rPFS in Cohort A patients treated with Lynparza was 7.4 months vs. 3.6 months in Xtandi or abiraterone treated patients (hazard ratio [HR]: 0.34; 95% CI: 0.25, 0.47; p < 0.0001).
    - In Cohort A, the objective response rate was 33% (95% CI: 23, 45) in Lynparza treated patients vs. 2% (95% CI: 0, 12) in Xtandi or abiraterone treated patients (p < 0.0001).
    - The median overall survival in Cohort A was 19.1 months in Lynparza treated patients vs. 14.7 months in Xtandi or abiraterone treated patients (HR: 0.69; 95% CI: 0.50, 0.97; p = 0.0175).
- The recommended dose of Lynparza for all indications is 300 mg orally twice daily, with or without food.
    - Information on FDA-approved tests for the detection of genetic mutations is available at http://www.fda.gov/companiondiagnostics.
    - For the treatment of HRR gene-mutated mCRPC, treatment should be continued until disease progression or unacceptable toxicity.
    - Patients receiving Lynparza for mCRPC should also receive a gonadotropin-releasing hormone analog concurrently or should have had bilateral orchiectomy.
    - Refer to the Lynparza drug label for further dosing recommendations for other indications.

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