Lynparza® (olaparib) – New indication

- On March 11, 2022, AstraZeneca announced the FDA approval of Lynparza (olaparib), for the adjuvant treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*m) human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy.
    - Patients should be selected for therapy based on an FDA-approved companion diagnostic for Lynparza.
- Lynparza is also approved for first-line maintenance treatment of *BRCA*-mutated advanced ovarian cancer; first-line maintenance treatment of homologous recombination deficiency (HRD)-positive advanced ovarian cancer in combination with bevacizumab; maintenance treatment of recurrent ovarian cancer; advanced g*BRCA*m ovarian cancer after 3 or more lines of chemotherapy; g*BRCA*m HER2-negative metastatic breast cancer; first-line maintenance treatment of g*BRCA*m metastatic pancreatic adenocarcinoma; and homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer.
- The approval of Lynparza for the new indication was based on a randomized, double-blind, placebo-controlled study in 1,836 patients with g*BRCA*m HER2-negative high risk early breast cancer who had completed definitive local treatment and neoadjuvant or adjuvant chemotherapy. The primary endpoint was invasive disease-free survival (IDFS), defined as the time from randomization to date of first recurrence, where recurrence is defined as invasive loco-regional, distant recurrence, contralateral invasive breast cancer, new cancer, or death from any cause. An additional efficacy outcome measure was overall survival (OS).
    - Lynparza demonstrated a statistically significant improvement in IDFS, reducing the risk of invasive breast cancer recurrences, second cancers or death, by 42% vs. placebo (based on a hazard ratio [HR] of 0.58, 95% CI: 0.46, 0.74; $p < 0.0001$).
    - Lynparza demonstrated a statistically significant improvement in OS, reducing the risk of death by 32% vs. placebo (based on a HR of 0.68, 95% CI: 0.50, 0.91; $p = 0.0091$).
- The recommended dosage of Lynparza is 300 mg taken orally twice daily. For adjuvant treatment of g*BRCA*m HER2-negative high risk early breast cancer, treatment should be continued for a total of 1 year, or until disease recurrence, or unacceptable toxicity, whichever occurs first. Patients receiving Lynparza for hormone receptor positive HER2-negative breast cancer should continue concurrent treatment with endocrine therapy as per current clinical practice guidelines.
    - Refer to the Lynparza drug label for dosing for all its other indications.