Lynparza® (olaparib) – New indication

- On December 30, 2019, AstraZeneca and Merck announced the FDA approval of Lynparza (olaparib), for the maintenance treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*m) metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.
    - Patients should be selected for therapy based on an FDA-approved companion diagnostic for Lynparza.
- Lynparza is also approved as first-line maintenance treatment of *BRCA*-mutated advanced ovarian cancer, maintenance treatment of recurrent ovarian cancer, advanced g*BRCA*m ovarian cancer after 3 or more lines of chemotherapy, and g*BRCA*m HER2-negative metastatic breast cancer.
- In the U.S., it is expected that more than 55,000 people will be diagnosed with pancreatic cancer and over 45,750 people will die of this disease. Globally, g*BRCA*m pancreatic cancer accounts for 5% to 7% of all cases.
    - Pancreatic cancer has the lowest survival rate of the most common cancers and is the only major cancer with a single-digit five-year survival rate (2% to 9%) in nearly every country.
- The approval of Lynparza for the new indication was based on POLO, a randomized, double-blind, placebo-controlled study in 154 patients with metastatic pancreatic adenocarcinoma with a deleterious or suspected deleterious g*BRCA*m. Patients were randomized to receive Lynparza or placebo until disease progression or unacceptable toxicity. The major efficacy outcome measure was progression-free survival (PFS). Additional efficacy outcome measures were overall survival (OS) and objective response rate (ORR).
    - Median PFS was 7.4 months for Lynparza vs. 3.8 months with placebo (hazard ratio 0.53; 95% CI: 0.35, 0.81; p = 0.0035).
    - The ORR was 23% (95% CI: 14, 34) and 12% (95% CI: 4, 23) for Lynparza and placebo, respectively.
    - The result of an OS interim analysis conducted based on 67% information fraction did not show a statistically significant improvement in OS for Lynparza vs. placebo.
- The recommended dose of Lynparza for all patients is 300 mg orally twice daily, with or without food. For patients with pancreatic adenocarcinoma, treatment should be continued until disease progression or unacceptable toxicity.
    - Refer to the Lynparza drug label for dosing duration for all its other indications.