## Lynparza® (olaparib) – New indication

- On December 19, 2018, AstraZeneca and Merck announced the FDA approval of Lynparza (olaparib) tablets for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated (*gBRCA*m or *sBRCA*m) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy.
    - Patients with *gBRCA*m advanced epithelial ovarian, fallopian tube or primary peritoneal cancer should be selected for therapy based on an FDA-approved companion diagnostic for Lynparza.
    - Lynparza is also approved for the maintenance treatment of recurrent ovarian cancer, advanced *gBRCA*-mutated ovarian cancer after 3 or more lines of chemotherapy, and for germline *BRCA*-mutated HER2-negative metastatic breast cancer.

- Ovarian cancer is a leading cause of cancer death in women worldwide, with a five-year survival rate of 19%. In 2018, there were over 295,000 new cases diagnosed and around 185,000 deaths.

- The new indication for Lynparza was based on data from a placebo-controlled study of 391 patients with *BRCA*-mutated advanced ovarian, fallopian tube, or primary peritoneal cancer following first-line platinum-based chemotherapy. The major efficacy outcome was progression-free survival (PFS).
    - The Lynparza group demonstrated a statistically significant improvement in PFS vs. placebo (HR: 0.30, 95% CI: 0.23 – 0.41; $p < 0.0001$).
    - The median PFS was 13.8 months with placebo and not reached with Lynparza.
    - At the time of the analysis of PFS, overall survival data were not mature (21% of patients had died).

- The recommended initial dose of Lynparza for all indications is 300 mg taken orally twice daily with or without food.
    - Treatment should be continued until disease progression, unacceptable toxicity, or completion of 2 years of treatment.
    - Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating healthcare provider can derive further benefit from continuous treatment, can be treated beyond 2 years.