Lynparza® (olaparib) – Voluntary indication withdrawal

- On August 26, 2022, the FDA approved a voluntary indication withdrawal for AstraZeneca's Lynparza (olaparib), for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.

- This decision does not affect the other approved indications for Lynparza, which include:

  - 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
  - Adjuvant treatment of germline BRCA-mutated human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer
  - Germline BRCA-mutated HER2-negative metastatic breast cancer
  - First-Line maintenance treatment of germline BRCA-mutated metastatic pancreatic adenocarcinoma
  - Homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer.