Zejula® (niraparib) – Indication removal

- On September 14, 2022, the FDA approved an indication removal for GlaxoSmithKline's Zejula (niraparib), for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with 3 or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency positive status defined by either: a deleterious or suspected deleterious *BRCA* mutation, or genomic instability and who have progressed more than 6 months after response to the last platinum-based chemotherapy.

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

    - Maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy
    - Maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.