Zejula® (niraparib) – Indication update

- On November 11, 2022, GSK announced an update that at the request of the FDA, it will restrict the second-line maintenance indication for Zejula (niraparib) to only the patient population with deleterious or suspected deleterious germline BRCA mutations (gBRCAmut).

- The US first-line indication of Zejula remains unchanged for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who have a complete or partial response to platinum-based chemotherapy.

- This decision follows an FDA review of the final overall survival (OS) analysis of the ENGOT-OV16/NOVA Phase 3 trial, which served as the basis for the approval of the second-line maintenance indication.

    — In the final OS results, the secondary endpoint of OS demonstrated a hazard ratio (HR) of 1.06 (95% CI: 0.81, 1.37) in the non-gBRCAmut cohort.