Zejula® (niraparib) – Expanded indication

- On October 23, 2019, GlaxoSmithKline announced the FDA approval of Zejula (niraparib), for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:

    - A deleterious or suspected deleterious *BRCA* mutation, or
    - Genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.
    - Select patients for therapy based on an FDA-approved companion diagnostic for Zejula.

- Zejula is also approved for the 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.

- The approval of Zejula for the expanded indication was based on QUADRA, a single-arm study in 98 patients with advanced ovarian cancer with HRD positive tumors. All patients received Zejula as monotherapy until disease progression or unacceptable toxicity. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR).

    - The overall ORR was 24% (95% CI: 16, 34). Median DOR was 8.3 months (95% CI: 6.5 to not estimable).

- The recommended dose of Zejula for all patients is 300 mg (three 100 mg capsules) taken orally once daily. Zejula treatment should be continued until disease progression or unacceptable toxicity.