Zejula® (niraparib) – New formulation approval

- On April 26, 2023, the FDA approved GSK's Zejula (niraparib) tablets, for the 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
    - Deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*mut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- Zejula was previously approved as a 100 mg oral capsule. The new oral tablet formulation will be available in a 100 mg, 200 mg, and 300 mg strength.
- For first-line maintenance treatment of advanced ovarian cancer, the recommended dose of Zejula is:
    - 200 mg taken orally once daily for patients weighing < 77 kg (< 170 lbs) OR with a platelet count of < 150,000/mcL
    - 300 mg taken orally once daily for patients weighing ≥ 77 kg (≥ 170 lbs) AND who have a platelet count ≥ 150,000/mcL
    - Patients should start treatment with Zejula no later than 12 weeks after their most recent platinum-containing regimen.
- For maintenance treatment of recurrent germline *BRCA*-mutated ovarian cancer, the recommended dose of Zejula is 300 mg taken orally once daily. Patients should start treatment with Zejula no later than 8 weeks after their most recent platinum-containing regimen.
- GSK's launch plans for Zejula tablets are pending.