Zejula® (niraparib) – Expanded indication

- On April 29, 2020, GlaxoSmithKline announced the FDA approval of Zejula (niraparib), 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.

- Zejula is also approved for maintenance treatment of recurrent ovarian cancer and treatment of advanced ovarian cancer after three or more chemotherapies.

- The approval of Zejula for the expanded indication was based on a double-blind, placebo-controlled study in 733 patients in complete or partial response to first-line platinum-based chemotherapy. Patients received Zejula or placebo. The major efficacy outcome measure was progression-free survival (PFS). Overall survival (OS) was an additional efficacy outcome measure. PFS testing was performed hierarchically: first in the homologous recombination deficiency (HRD) population, then in the overall population.

    - In the HRD population, median PFS was 21.9 months vs. 10.4 months for Zejula and placebo, respectively (hazard ratio [HR] 0.43; 95% CI: 0.31, 0.59; $p < 0.0001$).
    - In the overall population, median PFS was 13.8 months vs. 8.2 months for Zejula and placebo, respectively (HR 0.62; 95% CI: 0.50, 0.76; $p < 0.0001$).
    - At the time of the PFS analysis, OS data were immature with 11% deaths in the overall population.

- The recommended dose of Zejula for first-line maintenance treatment of advanced ovarian cancer is as follows:

    - For patients weighing less than 77 kg (170 lbs) OR with a platelet count of less than 150,000/µL: 200 mg (two 100-mg capsules) taken orally once daily.
    - For patients weighing greater than or equal to 77 kg (170 lbs) AND who have a platelet count greater than or equal to 150,000/µL: 300 mg (three 100-mg capsules) taken orally once daily.
    - For the maintenance treatment of advanced ovarian cancer, patients should start treatment with Zejula no later than 12 weeks after their most recent platinum-containing regimen.
    - Refer to the Zejula drug label for dosing for all its other uses.

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