14 September 2017
EMA/CHMP/574018/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zejula

niraparib

On 14 September 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zejula, intended for the maintenance treatment of ovarian cancer. Zejula was designated as an orphan medicinal product on 4 August 2010. The applicant for this medicinal product is Tesaro UK Limited.

Zejula will be available as capsules (100 mg). The active substance of Zejula is niraparib, an inhibitor of poly(ADP-ribose) polymerase (PARP) enzymes, PARP-1 and PARP-2, which play a role in DNA repair (ATC code: L01XX54). The inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes results in DNA damage and tumour cell death.

The benefits with Zejula are its ability to improve patients' progression-free survival compared with placebo. The most common side effects are nausea, thrombocytopenia, fatigue/asthenia, anaemia, constipation, vomiting, abdominal pain, neutropenia, insomnia, headache, decreased appetite, nasopharyngitis, diarrhoea, dyspnea, hypertension, dyspepsia, back pain, dizziness, cough, urinary tract infection, arthralgia, palpitations and dysgeusia.

The full indication is: "Zejula is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy."

It is proposed that Zejula be initiated and supervised by a physician experienced in the use of anticancer medicinal products.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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