26 April 2019
EMA/CHMP/232257/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Talzenna

talazoparib

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Talzenna, intended for the treatment of adult patients with germline BRCA1/2 mutations, who have HER2-negative locally advanced or metastatic breast cancer. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Talzenna will be available as hard capsules (0.25 and 1 mg). The active substance of Talzenna is talazoparib, an inhibitor of PARP enzymes, PARP1 and PARP2, which play a role in DNA repair (ATC code: L01XX60). The inhibition of PARP catalytic activity as well as PARP trapping, whereby a PARP enzyme bound to a PARP inhibitor does not readily dissociate from a DNA lesion, result in DNA damage and tumour cell death.

The benefits with Talzenna are its ability to improve patients' progression-free survival compared with chemotherapy. The most common side effects are fatigue, anaemia, nausea, neutropenia, thrombocytopenia, and headache.

The full indication is:

"Talzenna is indicated as monotherapy for the treatment of adult patients with germline BRCA1/2 mutations, who have HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo)adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments (see section 5.1). Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy."

It is proposed that Talzenna 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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