EMA/CHMP/55463/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Akeega

niraparib / abiraterone acetate

On 23 February 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Akeega, intended for the treatment of adult patients with metastatic castration-resistant prostate cancer with BRCA 1/BRCA 2 mutations. The applicant for this medicinal product is Janssen-Cilag International N.V.

Akeega will be available as film-coated tablets containing fixed-dose combinations of 50 mg niraparib / 500 mg abiraterone acetate or 100 mg niraparib / 500 mg abiraterone acetate. The active substances of Akeega are niraparib, an antineoplastic agent (ATC code: L01XK02) and abiraterone acetate, a hormone antagonist (L02BX03).

Niraparib inhibits the poly(ADP-ribose) polymerase (PARP) enzymes PARP-1 and PARP-2, which play a role in DNA repair. The inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes result in DNA damage and tumour cell death. Abiraterone acetate is converted to abiraterone, which inhibits 17α-hydroxylase/C17,20-lyase (CYP17), an enzyme required for androgen synthesis. By inhibiting CYP17, abiraterone acetate inhibits the production of androgens in the testes, adrenal glands and prostate.

The benefit of Akeega is its ability to delay disease progression compared to abiraterone acetate alone, as evaluated in a phase 3, randomized, placebo-controlled, double-blind study. The most common side effects are anaemia, hypertension, constipation, fatigue, nausea, thrombocytopenia, dyspnoea, back pain, decreased appetite, neutropenia, arthralgia, vomiting, hypokalaemia, dizziness, insomnia, hyperglycaemia and urinary tract infection.

The full indication is:

> Akeega is indicated with prednisone or prednisolone for the treatment of adult patients with metastatic castration resistant prostate cancer (mCRPC) and BRCA1/2 mutations (germline and/or somatic) in whom chemotherapy is not clinically indicated.

Akeega should be prescribed by physicians experienced in the treatment of prostate cancer.

[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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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.