22 March 2018
EMA/CHMP/723380/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rubraca

rucaparib

On 22 March 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Rubraca, intended for the treatment of relapsed or progressive ovarian cancer. Rubraca was designated as an orphan medicinal product on 10 October 2012. The applicant for this medicinal product is Clovis Oncology UK Ltd.

Rubraca will be available as 200 mg, 250 mg and 300 mg film-coated tablet. The active substance of Rubraca is rucaparib, an inhibitor of poly(ADP-ribose) polymerase (PARP) enzymes (ATC code: L01XX55) that blocks the repair of damaged DNA in cancer cells, and, as a result, causes the cancer cells to die.

The benefits with Rubraca are its anti-tumour activity as measured by objective response rate and response duration as well its safety profile. The most common side effects are fatigue, nausea, creatinine elevations, liver enzymes elevations, vomiting, anaemia, decreased appetite, dysgeusia, diarrhoea, and thrombocytopenia.

The full indication is: “monotherapy treatment of adult patients with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum based chemotherapy, and who are unable to tolerate further platinum based chemotherapy”.

It is proposed that Rubraca be prescribed by physicians 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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact