



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Lynparza olaparib

On 23 October 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lynparza, 50 mg hard capsules, intended for treatment of ovarian, fallopian tube and primary peritoneal cancers in women with BRCA mutations. Lynparza was designated an orphan medicinal product on 6 December 2007. The applicant for this medicinal product is AstraZeneca AB. They may request a re-examination of the CHMP opinion, provided they notify the European Medicines Agency of their intention within 15 days of receipt of the opinion.

The active substance of Lynparza is olaparib, an inhibitor of human poly (ADP ribose) polymerase enzymes (PARP-1, PARP-2, and PARP-3) required for the efficient repair of DNA single strand breaks. In normal cells, DNA single strand breaks can also be repaired by a process known as homologous recombination repair (HRR), which requires functional *BRCA1* and *BRCA2* genes. However, in cancer cells without functional *BRCA1* or *BRCA2*, single strand breaks cannot be repaired via HRR, making the cancer cells vulnerable to the inhibition of PARP by olaparib.

The main benefit of treatment with Lynparza is the improvement in progression-free survival among patients with platinum-sensitive, relapsed, high-grade serous epithelial ovarian, fallopian tube and primary peritoneal cancers with *BRCA* mutations. The most common side effects are nausea, vomiting, diarrhoea, dyspepsia, fatigue, headache, dysgeusia, decreased appetite, dizziness, anaemia, neutropenia, lymphopenia, corpuscular volume elevation, and increase in creatinine.

A pharmacovigilance plan for Lynparza will be implemented as part of the marketing authorisation.

The approved indication is: "monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed *BRCA*-mutated (germline and/or somatic) high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy".

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.



It is proposed that Lynparza 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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Lynparza and therefore recommends the granting of the marketing authorisation.