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Press Office

Press release

Lynparza recommended for approval in ovarian cancer

First-in-class medicine to provide new treatment option in patients with a *BRCA* mutation

The European Medicines Agency (EMA) has recommended granting a marketing authorisation for Lynparza (olaparib), a first-in-class medicine for the treatment of women with a subtype of ovarian cancer for which there are limited approved treatment options.

Ovarian cancer affects approximately 150,000 women in the European Union, and is the fifth most common cause of cancer death in women. Due to the absence of symptoms in early stages of the disease, the majority of patients are diagnosed when their cancer has already progressed, leading to a poor prognosis. Although several medicines are already authorised for this condition in the EU, there is still a need for new treatment options with novel modes of action. A significant proportion of patients respond to initial chemotherapy treatment. However, most ovarian cancers grow again and respond moderately or poorly to subsequent chemotherapy.

The Committee for Medicinal Products for Human Use (CHMP) recommended that Lynparza be used as monotherapy for the maintenance treatment of adult patients with relapsed, platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer with mutations in one of two genes called *BRCA,* and who have responded to platinum-based chemotherapy.

Lynparza is the first representative of a new class of medicines that blocks the action of proteins called PARP. PARP help to repair damaged DNA, including in tumour cells. If they are blocked, damaged DNA in a tumour cell cannot be repaired, and the tumour cell dies as a result. As a consequence, this medicine is expected to reduce tumour size or slow its growth. Lynparza is the first medicine against ovarian cancer specifically targeting forms of the disease carrying a mutation of the *BRCA* gene.

The CHMP's positive opinion is based on the results of a phase II pivotal study in patients with ovarian cancer with *BRCA* mutation, who had received two or more previous platinum-containing regimens. The Committee recommended a series of post-marketing measures, including requirements for the applicant to provide results from ongoing clinical trials as soon as they become available.

This positive opinion to authorise a medicine in a subtype of cancer based on the presence of certain genetic mutations highlights the current trend towards the development of medicines targeted at

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specific patient populations. This is a consequence of a better understanding of the underlying molecular mechanisms of the disease.

The Agency is actively supporting the development of medicines with new modes of action in areas of unmet medical need. Lynparza was designated as an orphan medicine and EMA provided protocol assistance to the applicant during the development of the medicine. Orphan designation and the associated incentives such as free scientific advice or protocol assistance are among the Agency's most important instruments to encourage the development of medicines for patients suffering from rare diseases.

The opinion adopted by the CHMP at its October 2014 meeting is an intermediary step on Lynparza's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Lynparza is AstraZeneca AB.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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