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AstraZeneca gains EU approval

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AstraZeneca has announced that the European Commission (EC) has granted marketing authorization for Lynparza (olaparib) capsules (400mg twice daily) as the first therapy for 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 complete response or partial response to platinum-based chemotherapy.

Olaparib is a poly ADP-ribose polymerase (PARP) inhibitor that exploits tumour DNA repair pathway deficiencies to preferentially kill cancer cells. It is the first PARP inhibitor to be approved for patients with platinum-sensitive relapsed BRCA-mutated ovarian cancer.

"We are delighted to be able to bring this much needed treatment to patients with BRCA-mutated ovarian cancer whose options are currently very limited. Today's approval marks a significant milestone in the development of the next generation of targeted medicines. We are committed to bringing new treatments to the patients who need them most and today's news marks only the first of what we hope will be a number of indications in which Lynparza has the potential to transform the lives of cancer patients, including those with breast, pancreatic and gastric cancers," said Mr Briggs Morrison, executive vice president, Global Medicines Development and chief medical oficer at AstraZeneca.

The EC decision is applicable to all 28 EU member states as well as Norway, Iceland and Liechtenstein. The approval of olaparib was based on data from Study 191, a Phase II clinical trial that evaluated its efficacy and safety compared to placebo in platinum-sensitive relapsed high grade serous ovarian cancer patients. The study showed that olaparib maintenance therapy significantly prolonged progression free survival (PFS) compared with placebo in patients with BRCA-mutated ovarian cancer.

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