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AstraZeneca's Lynparza gets FDA priority review for PAOLA-1

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AstraZeneca and MSD Inc. have announced that a supplemental New Drug Application for *Lynparza* (olaparib) in combination with bevacizumab has been accepted and granted Priority Review in the US for the maintenance treatment of patients with advanced ovarian cancer who are in complete or partial response to 1st-line platinum-based chemotherapy with bevacizumab.

A Prescription Drug User Fee Act (PDUFA) date is set for the second quarter of 2020.

The Priority Review by the US Food and Drug Administration (FDA) was based on results from the pivotal Phase III PAOLA-1 trial. The trial compared *Lynparza* when added to standard-of-care (SoC) bevacizumab vs. bevacizumab alone in patients with advanced ovarian cancer in the 1st-line maintenance setting, regardless of their biomarker status or outcome from previous surgery.

The investigator-assessed results showed *Lynparza* added to bevacizumab reduced the risk of disease progression or death by 41% based on a hazard ratio of 0.59 ($p<0.0001$) and improved progression-free survival (PFS) to a median of 22.1 months vs. 16.6 months for patients treated with bevacizumab alone.

At two years after trial initiation, 46% of patients treated with *Lynparza* added to bevacizumab showed no disease progression vs. 28% of patients treated with bevacizumab alone. The safety and tolerability profiles of *Lynparza* and bevacizumab were consistent with previous trials for each medicine and showed no detriment to quality of life.

Lynparza is the only PARP inhibitor with two positive randomised Phase III trials in the 1st-line maintenance setting for advanced ovarian cancer. It is the only PARP inhibitor approved in the US as a 1st-line maintenance treatment for patients with BRCA-mutated advanced ovarian cancer, based on the SOLO-1 trial. If approved, this would be the fourth indication for ovarian cancer patients in the US for *Lynparza*.