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AstraZeneca receives Chinese marketing nod for Lynparza

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Lynparza approved in China as a 1st-line maintenance therapy in BRCA-mutated advanced ovarian cancer

AstraZeneca and MSD have announced that the companies have received marketing authorisation from China's National Medical Products Administration (NMPA) for *Lynparza* (olaparib) as a 1st-line maintenance treatment of adult patients with newly diagnosed advanced germline or somatic BRCA mutated (gBRCAm or sBRCAm) epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to 1st-line platinum-based chemotherapy.

The approval in China is based on the results from the Phase III SOLO-1 trial, which were published in *The New England Journal of Medicine.* Results showed that *Lynparza* significantly reduced the risk of disease progression or death by 70% (equal to a hazard ratio of 0.30) vs. placebo in women with BRCAm advanced ovarian cancer following response to platinum-based chemotherapy. Of those women receiving *Lynparza*, 60% remained progression-free at three years vs. 27% of women receiving placebo.

For newly diagnosed advanced ovarian cancer patients, the primary aim of treatment is to delay progression of the disease for as long as possible, with the intent of achieving complete remission or cure. Of women diagnosed with ovarian cancer, 15% have a germline (inherited) mutation and 7% have a somatic (acquired) mutation in their BRCA1/2 genes.

Dave Fredrickson, Executive Vice President, Oncology Business Unit, said: "This approval marks a new era for women with BRCA-mutated advanced ovarian cancer in China, where the prevalence of BRCA mutations in advanced disease is higher than the international average. Currently, 70% of women relapse within three years of initial treatment, representing the highest reoccurrence rate among gynaecological cancers worldwide. The progression-free survival benefit of *Lynparza* observed in SOLO-1 is a significant step towards helping these women achieves long-term remission."

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: "Today's approval of *Lynparza* reinforces the importance of patients knowing their BRCA mutation status at diagnosis. We are proud to provide a new option for the treatment of this devastating disease in China, and we will continue to collaborate with the Chinese government and healthcare organisations to provide *Lynparza* to patients who need

it as quickly as possible."

Lynparza is the first PARP inhibitor approved in China for 1st-line maintenance in BRCAm advanced ovarian cancer. AstraZeneca and MSD are exploring additional trials in ovarian cancer and recently announced positive results from the Phase III PAOLA-1 trial, which tested *Lynparza* in combination with bevacizumab as a 1st-line maintenance treatment for women with newly-diagnosed advanced ovarian cancer, regardless of their biomarker status or surgical outcome.