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AstraZeneca bags DCGI approval for Lynparza to treat early breast cancer

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Lynparza is the first and only approved PARPi targeting BRCA-mutated HER2-negative high-risk early breast cancer

AstraZeneca India has received Drugs Controller General of India (DCGI) approval to market its drug Lynparza (Olaparib) as a monotherapy for the adjuvant treatment of adult patients with BRCA-mutated HER2- negative high-risk early breast cancer, who have previously been treated with neoadjuvant or adjuvant chemotherapy.

The approval was based on results from the OlympiA Phase III trial, which suggested that Olaparib demonstrated a statistically significant and clinically meaningful improvement, with an overall survival benefit. With the DCGI's approval, Lynparza is now approved in the US, EU, Japan, India and several other countries for the treatment of the same. Currently, Lynparza is the first and only approved medicine targeting BRCA mutations in early-stage breast cancer.

The results from the landmark OlympiA Phase III trial highlight the value and importance of testing for BRCA mutations at diagnosis. Olaparib demonstrated a statistically significant and clinically meaningful improvement in invasive disease-free survival (iDFS), reducing the risk of invasive breast cancer recurrences, second cancers or death by 42 per cent versus placebo. The newly updated results from the OlympiA trial also showed Lynparza demonstrated a statistically significant and clinically meaningful improvement in the key secondary endpoint of overall survival (OS), reducing the risk of death by 32% versus placebo.