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Japan gives nod to breast cancer drug by AstraZeneca and Merck

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Adjuvant treatment for patients With BRCA-mutated, HER2-negative high recurrent risk breast cancer

AstraZeneca and Merck, known as MSD outside of the United States and Canada, have announced that LYNPARZA has been approved by the Japan Pharmaceuticals and Medical Devices Agency (PMDA) for the adjuvant treatment for patients with BRCA-mutated (BRCAm), human epidermal growth factor receptor 2 (HER2)-negative high recurrent risk breast cancer.

This approval was based on results from the Phase 3 OlympiA trial published in The New England Journal of Medicine in June 2021. In the trial, LYNPARZA demonstrated a statistically significant and clinically meaningful improvement in invasive disease-free survival (IDFS), reducing the risk of invasive breast cancer recurrences, new cancers, or death by 42% versus placebo.

Over 90% of all breast cancer patients in Japan are diagnosed with early breast cancer. BRCA mutations are found in approximately 10% of HER2-negative patients.

LYNPARZA is also approved in the US, EU, Japan and several other countries for the treatment of adult patients with gBRCAm, HER2-negative, metastatic breast cancer previously treated with chemotherapy and, if hormone receptor-positive, endocrine therapy if appropriate based on results from the Phase 3 OlympiAD trial. In the EU, this indication also includes patients with locally advanced breast cancer.