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ASIA EDITION

FDA approves first treatment for breast cancer with a certain inherited genetic mutation

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It is the first time any drug has been approved to treat certain patients with metastatic breast cancer who have a "BRCA" gene mutation.

Singapore - The U.S. Food and Drug Administration expanded the approved use of Lynparza (olaparib tablets) to include the treatment of patients with certain types of breast cancer that have spread (metastasized) and whose tumors have a specific inherited (germline) genetic mutation, making it the first drug in its class (PARP inhibitor) approved to treat breast cancer, and it is the first time any drug has been approved to treat certain patients with metastatic breast cancer who have a "BRCA" gene mutation. Patients are selected for treatment with Lynparza based on an FDA-approved genetic test, called the BRACAnalysis CDx.

"This class of drugs has been used to treat advanced, BRCA-mutated ovarian cancer and has now shown efficacy in treating certain types of BRCA-mutated breast cancer," said Richard Pazdur, M.D., director of the FDA's Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "This approval demonstrates the current paradigm of developing drugs that target the underlying genetic causes of a cancer, often across cancer types."

Breast cancer is the most common form of cancer in the United States. The National Cancer Institute at the National Institutes of Health estimates approximately 252,710 women will be diagnosed with breast cancer this year, and 40,610 will die of the disease. Approximately 20-25 percent of patients with hereditary breast cancers and 5-10 percent of patients with any type of breast cancer have a BRCA mutation. BRCA genes are involved with repairing damaged DNA and normally work to prevent tumor development. However, mutations of these genes may lead to certain cancers, including breast cancers.

Lynparza is a PARP (poly ADP-ribose polymerase) inhibitor that blocks an enzyme involved in repairing damaged DNA. By blocking this enzyme, DNA inside the cancerous cells with damaged BRCA genes may be less likely to be repaired, leading to cell death and possibly a slow-down or stoppage of tumor growth. Lynparza was first approved by the FDA in 2014 to treat certain patients with ovarian cancer and is now indicated for the treatment of patients with germline breast cancer susceptibility gene (BRCA) mutated, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer, who have been previously treated with chemotherapy. Patients with hormone

receptor (HR)-positive breast cancer should have been treated with a prior hormonal (endocrine) therapy or be considered inappropriate for endocrine treatment.

Lynparza is also approved for the treatment of patients with BRCA-mutated, advanced ovarian cancer who have received three or more treatments of chemotherapy, and for the maintenance treatment of patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer whose tumors have completely or partially responded to chemotherapy.

The FDA granted the approval of Lynparza to AstraZeneca Pharmaceuticals LP. The approval of the BRACAnalysis CDx was granted to Myriad Genetic Laboratories, Inc.