First Treatment Approved for Breast Cancer with BRCA Genetic Mutation

The Food and Drug Administration on Friday cleared the first treatment for patients with advanced breast cancer caused by BRCA mutations, which are genetic defects that raise the risk of malignancies.

The drug, called Lynparza, already is approved for certain patients with advanced ovarian cancer associated with the same mutations. Richard Pazdur, director of the FDA's Oncology Center of Excellence, said in a statement that expanding the approval to breast-cancer patients "demonstrates the current paradigm of developing drugs that target the underlying genetic causes of a cancer, often across cancer types."

Lynparza belongs to a class of drugs called PARP inhibitors that block an enzyme involved in repairing damaged DNA. By blocking the enzyme, the DNA in cancer cells may be less likely to be fixed, leading to the death of those cells and potentially a slowdown or halt in tumor growth, the FDA said. The drug, also known as olaparib, is marketed by AstraZeneca and Merck.

The agency said its approval was based on a randomized clinical trial of more than 300 advanced breast cancer patients with BRCA 1 or BRCA 2 mutations. The trial found that the length of time during which the tumors did not grow significantly, a measure called progression-free survival, was a median of 7 months for patients treated with Lynparza compared to 4.2 months for patients receiving chemotherapy only. Lynparza didn't improve the overall length of survival, however.

McGinley, Laurie.(2018) First Treatment Approved for Breast Cancer with BRCA Genetic Mutation. The Washington Post. Retrieved 1/14/2018 from: https://www.washingtonpost.com/news/to-your-health/wp/2018/01/12/first-treatment-approved-for-breast-cancer-with-brca-genetic-mutation/?utm_term=.5ac830621665