

FDA approves first drug for tumors tied to breast cancer genes

January 12 2018



(HealthDay)—The U.S. Food and Drug Administration on Friday

approved the first drug aimed at treating metastatic breast cancers linked to the BRCA gene mutation.

These mutated genes, called BRCA1 and BRCA2, first came to prominence in 2013 when actress and director Angelina Jolie announced she'd undergone a preventive double mastectomy. Jolie said she carried the BRCA1 gene, which greatly raises a woman's odds for [breast](#) and [ovarian cancers](#).

Now, the FDA says it is expanding approval of Lynparza (olaparib) to include use against BRCA-linked tumors that have spread beyond the breast.

Lynparza is one of a group of powerful new [cancer](#) drugs known as PARP inhibitors, and it's the first such [drug](#) to be approved for use against breast cancer, the FDA noted. Lynparza is already approved to treat certain ovarian cancers.

PARP inhibitors have already "been used to treat advanced, BRCA-mutated ovarian cancer and have now shown efficacy in treating certain types of BRCA-mutated breast cancer," Dr. Richard Pazdur, who directs the FDA's Oncology Center of Excellence, explained in an agency news release.

"This approval demonstrates the current paradigm of developing drugs that target the underlying genetic causes of a cancer, often across cancer types," he added.

According to the FDA, BRCA mutations are involved in up to one in every four breast cancers that are thought to have a hereditary component. These aberrant genes are also implicated in between 5 and 10 percent of non-hereditary breast tumors, the agency said.

When it's functioning properly, BRCA actually helps repair damaged cellular DNA and prevent tumors, but when BRCA1 and BRCA2 go awry they instead encourage breast cancers.

PARP inhibitor medicines such as Lynparza appear to interfere with the function of mutated BRCA with breast cells, causing them to die rather than replicate—slowing tumor growth, the FDA explained.

The safety and effectiveness of Lynparza for women with advanced BRCA-linked breast cancers was established after a trial of more than 300 patients.

"The trial measured the length of time the tumors did not have significant growth after treatment [progression-free survival]," the agency explained. "The median progression-free survival for patients taking Lynparza was 7 months compared to 4.2 months for patients taking chemotherapy only."

Lynparza does come with side effects, which can include anemia, low white blood cell counts, nausea, fatigue, vomiting, headache, joint pain, increased susceptibility to colds and other respiratory tract infections, and other effects. Because Lynparza can harm a developing fetus, women are advised to use contraception while on the drug. Women should also not breast-feed while using Lynparza, the FDA said.

The drug is made by AstraZeneca.

Along with the expanded approval of Lynparza, the FDA said it has "also expanded the approval of the BRCA Analysis CDx, an approved companion diagnostic to Lynparza, to include the detection of BRCA mutations in blood samples from patients with breast cancer."

In related news, a study published Jan. 11 in *The Lancet Oncology* found

that young [breast cancer](#) patients who carry a BRCA mutation do not have shorter survival when compared to patients without the mutation.

The study, which followed more than 2,700 [patients](#) for 10 years, was led by Diana Eccles from the University of Southampton in England.

More information: Find out more about BRCA1 and BRCA2 at the [U.S. National Cancer Institute](#).

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Citation: FDA approves first drug for tumors tied to breast cancer genes (2018, January 12)
retrieved 3 February 2024 from

<https://medicalxpress.com/news/2018-01-fda-drug-tumors-tied-breast.html>

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