Medical Xpress

AstraZeneca cancer drug, companion test approved

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U.S. regulators on Friday granted accelerated approval to the first in a new class of targeted drugs for ovarian cancer, Lynparza from British drugmaker AstraZeneca PLC.

The drug is for women whose ovarian cancer is associated with certain defective genes and whose cancer persists after multiple treatments.

Women with mutated BRCA genes have a higher risk of getting ovarian cancer. About 10 percent to 15 percent of ovarian cancer cases are due to those hereditary mutations.

The Food and Drug Administration also approved a companion diagnostic test from Myriad Genetics Inc. of Salt Lake City called BRACAnalysis CDx. The test is to be used to identify women most likely to benefit from the new medication.

Lynparza, known chemically as olaparib, is the first medicine in a new class called PARP inhibitors, short for poly ADP-ribose polymerase inhibitors. They work by blocking enzymes involved in repairing damaged DNA.

Each year, nearly 22,000 American women are diagnosed with ovarian cancer and more than 14,000 die from it, according to National Cancer Institute estimates.

Dr. Richard Pazdur, director of the FDA's Office of Hematology and

Oncology Products, called Lynparza "an example of how a greater understanding of the underlying mechanisms of disease can lead to targeted, more personalized treatment."

The drug was tested in 137 ovarian cancer patients with the genetic mutation, with 34 percent having their tumors shrink or disappear for an average of 7.9 months.

In a statement, Astra Zeneca said the approval strengthens its growing portfolio of cancer drugs and is good news for patients, "as currently the prognosis for ovarian cancer patients is poor and treatment options are progressively limited with each additional line of therapy."

Side effects range from nausea, fatigue, diarrhea and distorted taste to less-common, more-serious problems including lung inflammation, a bone marrow cancer called acute myeloid leukemia and myelodysplastic syndrome, a disorder in which bone marrow can't produce enough functioning blood cells.

The FDA's accelerated approval program gives patients earlier access to promising new drugs while their developer conducts additional patient testing to confirm early results.

Myriad's diagnostic test uses DNA from a blood sample to identify harmful or suspicious mutations in the BRCA1 and BRCA2 genes. Patient tests showed it is effective in identifying patients with those mutations.

Mark Capone, president of Myriad Genetic Laboratories, said in a statement that the diagnostic test "opens a new door in personalized medicine and represents a big step forward in tailoring treatment for women with ovarian cancer."

A Myriad spokesman said the test has a list price of $4,040, though most women with insurance pay nothing. Astra Zeneca said Lynparza's cost will be comparable to other pills for cancer; many now cost tens of thousands of dollars for a course of treatment.

Both companies offer eligible patients financial assistance.

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