FDA News Release

FDA approves maintenance treatment for recurrent epithelial ovarian, fallopian tube or primary peritoneal cancers

For Immediate Release

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Release

The U.S. Food and Drug Administration today approved Zejula (niraparib) for the maintenance treatment (intended to delay cancer growth) of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, whose tumors have completely or partially shrunk (complete or partial response, respectively) in response to platinum-based chemotherapy.

“Maintenance therapy is an important part of a cancer treatment regimen for patients who have responded positively to a primary treatment,” said Richard Pazdur, M.D., acting director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research and director of the FDA’s Oncology Center of Excellence. “Zejula offers patients a new treatment option that may help delay the future growth of these cancers, regardless of whether they have a specific genetic mutation.”

Epithelial ovarian, fallopian tube or primary peritoneal cancer is a cancer of the tissue covering the ovary or lining the fallopian tube or abdominal wall (peritoneum). The National Cancer Institute estimates that more than 22,000 women will be diagnosed with these cancers in 2017 and more than 14,000 will die of these diseases.

Zejula is a poly ADP-ribose polymerase (PARP) inhibitor that blocks an enzyme involved in repairing damaged DNA. By blocking this enzyme, DNA inside the cancerous cells may be less likely to be repaired, leading to cell death and possibly a slow-down or stoppage of tumor growth.

The safety and efficacy of Zejula were studied in a randomized trial of 553 patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who had received at least two prior treatments of platinum-based chemotherapy and who had experienced a complete or partial response to their most recent chemotherapy treatment. Patients were tested with an FDA-approved test to determine whether they had a specific gene mutation, called a deleterious or germline BRCA mutation. The trial measured the length of time the patients’ tumors did not grow after treatment (progression-free survival) in patients with and without the mutation. The median progression-free survival for patients taking Zejula who had a germline BRCA mutation was 21 months compared to 5.5 months for the same patient population taking a placebo. The median progression-free survival for patients taking Zejula who did not have a germline BRCA mutation was 9.3 months compared to 3.9 months for the same patient population taking a placebo.

Common side effects of Zejula include low levels of red blood cells (anemia), low levels of blood platelets (thrombocytopenia), low levels of white blood cells (neutropenia or leukopenia), heart palpitations, nausea, constipation, vomiting, abdominal pain/swelling (distention), inflammation of the mucous membranes (mucositis),

diarrhea, indigestion (dyspepsia), dry mouth, fatigue, decreased appetite, urinary tract infection, liver problems (AST/ALT elevation), muscle pain (myalgia), back pain, joint pain (arthralgia), headache, dizziness, unusual taste sensation (dysgeusia), insomnia, anxiety, cold-like symptoms (nasopharyngitis), trouble breathing (dyspnea), cough, rash and high blood pressure (hypertension). Zejula is associated with serious risks, such as hypertension, severe increase in blood pressure (hypertensive crisis), bone marrow problems (myelodysplastic syndrome), a type of cancer of the blood called acute myeloid leukemia and low levels of blood cells in the bone marrow (bone marrow suppression).Women who are pregnant or breastfeeding should not take Zejula because it may cause harm to a developing fetus or a newborn baby.

The FDA granted this application **Fast Track (/ForPatients/Approvals/Fast/ucm405399.htm)**, **Priority Review (/ForPatients/Approvals/Fast/ucm405405.htm)** and **Breakthrough Therapy (/ForPatients/Approvals/Fast/ucm405397.htm)** designations.

Zejula also received **Orphan Drug (/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm)** designation specifically for its use in treating recurrent epithelial ovarian cancer. This designation provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted the approval of Zejula to Tesaro, Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- **FDA: Office of Hematology and Oncology Products (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm091745.htm)**
- **FDA: Approved Drugs: Questions and Answers (/Drugs/ResourcesForYou/Consumers/ucm054420.htm)**
- **FDA: Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review (/ForPatients/Approvals/Fast/default.htm)**
- **NCI: Ovarian epithelial, fallopian tube and primary peritoneal cancer (https://www.cancer.gov/types/ovarian/patient/ovarian-epithelial-treatment-pdq)**