

## FDA News Release

# FDA approves new treatment for adults with relapsed follicular lymphoma

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## For Immediate Release

September 14, 2017

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## Release

The U.S. Food and Drug Administration today granted accelerated approval to Aliqopa (copanlisib) for the treatment of adults with relapsed follicular lymphoma who have received at least two prior treatments known as systemic therapies.

“For patients with relapsed follicular lymphoma, the cancer often comes back even after multiple treatments,” 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. “Options are limited for these patients and today’s approval provides an additional choice for treatment, filling an unmet need for them.”

Follicular lymphoma is a slow-growing type of non-Hodgkin lymphoma, a cancer of the lymph system. The lymph system is part of the body’s immune system and is made up of lymph tissue, lymph nodes, the spleen, thymus, tonsils and bone marrow. The National Cancer Institute at the National Institutes of Health estimates that approximately 72,240 people in the United States will be diagnosed with some form of non-Hodgkin lymphoma this year; approximately 20,140 patients with non-Hodgkin lymphoma will die from the disease in 2017.

Aliqopa is a kinase inhibitor that works by blocking several enzymes that promote cell growth.

Aliqopa received an **[Accelerated Approval \(/ForPatients/Approvals/Fast/ucm405447.htm\)](#)**, which enables the FDA to approve drugs for serious conditions to fill an unmet medical need using clinical trial data that is thought to predict a clinical benefit to patients. Further clinical trials are required to confirm Aliqopa’s clinical benefit and the sponsor is currently conducting these studies.

Today’s approval of Aliqopa was based on data from a single-arm trial that included 104 patients with follicular B-cell non-Hodgkin lymphoma who had relapsed disease following at least two prior treatments. The trial measured how many patients experienced complete or partial shrinkage of their tumors after treatment (overall response rate). In the trial, 59 percent of patients had a complete or partial response for a median 12.2 months.

Common side effects of Aliqopa include high blood sugar levels (hyperglycemia), diarrhea, decreased general strength and energy, high blood pressure (hypertension), low levels of certain white blood cells (leukopenia, neutropenia), nausea, lower respiratory tract infections, and low levels of blood platelets (thrombocytopenia).

Serious side effects include infections, high blood sugar levels (hyperglycemia), high blood pressure (hypertension), inflammation of the lung tissue (non-infectious pneumonitis), low levels of certain white blood cells (neutropenia), and severe skin reactions. Women who are pregnant or breastfeeding should not take Aliqopa because it may cause harm to a developing fetus or newborn baby.

Aliqopa was granted **Priority Review ([/ForPatients/Approvals/Fast/ucm405405.htm](http://www.fda.gov/ForPatients/Approvals/Fast/ucm405405.htm))** designation, under which the FDA's goal is to take action on an application within six months where the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing or preventing a serious condition.

Aliqopa also received **Orphan Drug (<http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm>)** designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

The FDA granted the approval of Aliqopa to Bayer Healthcare Pharmaceuticals, 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 \(\[/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm091745.htm\]\(http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm091745.htm\)\)](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm091745.htm)**
- **[FDA: Approved Drugs: Questions and Answers \(\[/Drugs/ResourcesForYou/Consumers/ucm054420.htm\]\(http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm054420.htm\)\)](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm054420.htm)**
- **[FDA: Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review \(<https://www.fda.gov/ForPatients/Approvals/Fast/default.htm>\)](https://www.fda.gov/ForPatients/Approvals/Fast/default.htm)**
- **[NCI: Adult non-Hodgkin Lymphoma \(<https://www.cancer.gov/types/lymphoma/patient/adult-nhl-treatment-pdq>\)](https://www.cancer.gov/types/lymphoma/patient/adult-nhl-treatment-pdq)**

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