COMMUNICATION

COM-2023-070

21
NOVEMBER
2023

PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 219.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Aliqopa™ Withdrawal from the Market

Bayer announced on November 13, 2023, the decision of a voluntary withdrawal of Aliqopa™ (copanlisib) from the U.S. market. The decision came after failure to meet the goal of progression-free survival established in a clinical trial.

Background:

Aliqopa™ (copanlisib) is a kinase inhibitor indicated for the treatment of adult patients with relapsed follicular lymphoma who have received at least two prior systemic therapies. It is an intravenous infusion that comes in a single-dose vial for reconstitution. The usual dosage is 60 mg administered as a 1-hour intravenous infusion on Days 1, 8, and 15 of a 28-day treatment cycle.

Aliqopa™ was granted accelerated approval from the U.S. Food and Drug Administration (FDA) in September 2017. Accelerated approval was instituted by the FDA to allow for earlier approval of drugs that treat serious, life-threatening conditions, as is the case with follicular lymphoma. This accelerated approval came from the results from CHRONOS-1, an open label, single-arm Phase II study. In the study, more than half (59%) of patients achieved complete or partial response to copanlisib.

The withdrawal:

As with any drug that goes through the process of accelerated approval, a confirmatory trial is still required to confirm the anticipated clinical benefits. If a confirmatory trial does not show that a drug provides clinical benefit, the FDA could require that the drug company removes such drug from the market.

In the case of Aliqopa™, the FDA required Bayer to show confirmed clinical benefit through the phase 3 CHRONOS-4 study. The study evaluated the addition of Aliqopa™ to standard immunochemotherapy regimens versus the standard immunochemotherapy in patients with relapsed follicular lymphoma. The decision to withdraw Aliqopa™ was made since the confirmatory trial failed to meet the primary endpoint of progression free survival.

Bayer indicates that Aliqopa™ should not be prescribed to new patients and that is looking for ways to continue to provide access to the treatment for those who have experienced favorable response to such treatment. For now, patients that are taking this medication should continue treatment unless specified otherwise by their healthcare provider.

Additional information can be found at: www.bayer.com/en/us/news-stories/update-on-aliqopar or by calling directly to Bayer Medical Communications at 1-888-84-Bayer.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext 219. Our pharmacists will help you. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:

1. Bayer. (2023, November 13). Bayer provides update on Aliqopa® (COPANLISIB). Bayer United States. https://www.bayer.com/en/us/news-stories/update-on-aliqopar
2. Formulary Watch. (2023, November 13). Bayer to withdraw cancer drug Aliqopa from market. https://www.formularywatch.com/view/bayer-to-withdraw-cancer-drug-aliqopa-from-market
3. Chronos-1: Copanlisib shows promise for patients with relapsed/refractory indolent B-cell NHL. ASH Clinical News | American Society of Hematology. (2021, December 30). https://ashpublications.org/ashclinicalnews/news/3082/CHRONOS-1-Copanlisib-Shows-Promise-for-Patients

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