FDA Requests the Withdrawal of Belviq, Belviq XR (Lorcaserin) From the Market

Potential risk of cancer outweighs the benefits

February 13, 2020 By Food and Drug Administration (FDA)

This is an update to the FDA Drug Safety Communication: Safety clinical trial shows possible increased risk of cancer with weight-loss medicine Belviq, Belviq XR (lorcaserin) issued on January 14, 2020.

2-13-2020 FDA Drug Safety Communication

What safety concern is FDA announcing?

The U.S. Food and Drug Administration (FDA) has requested that the manufacturer of Belviq, Belviq XR (lorcaserin) voluntarily withdraw the weight-loss drug from the U.S. market because a safety clinical trial shows an increased occurrence of cancer. The drug manufacturer, Eisai Inc., has submitted a request to voluntarily withdraw the drug.

What is FDA doing?

We are taking this action because we believe that the risks of lorcaserin outweigh its benefits based on our completed review of results from a randomized clinical trial assessing safety.

In January 2020, we announced we were reviewing clinical trial data and alerted the public about a possible risk of cancer associated with lorcaserin based on preliminary analysis of the data.

What should patients do?

Patients should stop taking lorcaserin and talk to your health care professionals about alternative weight-loss medicines and weight management programs. It's best to dispose of unused lorcaserin using a drug take back location, but if you can't get to one you can dispose of lorcaserin in your household trash:

1. Mix the pills with an unappealing substance such as dirt, cat litter, or used coffee grounds; do not crush them.
2. Place the mixture in a container such as a sealed plastic bag.
3. Throw away the container in your trash at home.
4. Remove or delete all personal information on the prescription label of empty medicine bottles or packaging, then throw away or recycle them.

FDA is not recommending special screening for patients who have taken lorcaserin. Talk to your health care professional if you have questions.

What should health care professionals do?

Health care professionals should stop prescribing and dispensing lorcaserin to patients. Contact patients currently taking lorcaserin, inform them of the increased occurrence of cancer seen in the clinical trial, and ask them to stop taking the medicine. Discuss alternative weight-loss medicines or strategies with your patients.

FDA is not recommending special screening for patients who have taken lorcaserin. As with any individual patient, regardless of prior lorcaserin treatment, standard screening recommendations for cancer should be implemented.

What did FDA find?

When FDA approved lorcaserin in 2012, we required the drug manufacturer to conduct a randomized, double-blind, placebo-controlled clinical trial to evaluate the risk of cardiovascular problems, which found that more patients taking lorcaserin (n=462; 7.7 percent) were diagnosed with cancer compared to those taking a placebo, which is an inactive treatment (n=423; 7.1 percent). The trial was conducted in 12,000 patients over 5 years. A range of cancer types was reported, with several different types of cancers occurring more frequently in the lorcaserin group, including pancreatic, colorectal, and lung.

How do I report side effects from lorcaserin?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving lorcaserin or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Data Summary

We reviewed data from the Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients – Thrombolysis in Myocardial Infarction 61 (CAMELLIA-TIMI 61) clinical trial. It was a randomized, double-blind, placebo-controlled, multicenter, parallel group trial conducted between January 2014 and June 2018 in the U.S., Canada, Mexico, the Bahamas, Europe, South America, Australia, and New Zealand. The study population consisted of 12,000 men and women who were overweight or obese. Patients were required to have either established cardiovascular disease, or to be at least 50 years old for men or 55 years for women with type 2 diabetes mellitus plus at least one additional cardiovascular risk factor. Eligible patients were assigned randomly to either lorcaserin 10 mg twice daily or placebo. Approximately 96 percent of patients completed the study, and 62 percent who completed remained on treatment at the end of study. The median follow-up time was 3 years and 3 months.

The primary safety analysis showed no meaningful difference between lorcaserin and placebo in the risk of major adverse cardiovascular events, demonstrating noninferiority. The one-sided upper

bound of the 95% confidence interval (CI) of the hazard ratio (HR) was less than 1.4 (the noninferiority margin). The HR (95% CI) was 1.005 (0.842, 1.198) for lorcaserin versus placebo.

There was a numerical imbalance in the number of patients with malignancies, with one additional cancer observed per 470 patients treated for one year. During the course of the trial, 462 (7.7 percent) patients treated with lorcaserin were diagnosed with 520 primary cancers compared to the placebo group, in which 423 (7.1 percent) patients were diagnosed with 470 cancers. Imbalances in specific cancers including pancreatic, colorectal, and lung contributed to the observed overall imbalance in cancer cases. There was no apparent difference in the incidence of cancer over the initial months of treatment, but the imbalance increased with longer duration on lorcaserin.

Related Information

National Cancer Institute: Cancer Screening Tests

Medline Plus: Obesity

The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective

Think It Through: Managing the Benefits and Risks of Medicines

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