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CLINICAL UPDATE

Brand Name	Belviq; Belviq XR
Generic Name	lorcaserin

Clinical Update

FDA requests the withdrawal of the weight-loss drug Belviq, Belviq XR (lorcaserin) from the market.

FDA Approval Date: February 13, 2012

Safety

Lorcaserin is a weight-loss medicine used by the people to treat obesity. FDA announced that they 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. Later in 2020 FDA requested 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 which outweighs its benefits.

FDA 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.

FDA has advised patients who are currently using/taking lorcaserin to immediately stop it, and should talk to their health care professionals about alternative weight-loss medicines and weight management programs.

It is suggested that the unused lorcaserin should be disposed using a drug take back location or by disposing lorcaserin in household trash.