Eisai – Withdrawal of Belviq®, Belviq XR (lorcaserin)

- On February 13, 2020, the FDA announced the request to voluntarily withdraw Belviq, Belviq XR (lorcaserin) from the U.S. market because a safety clinical trial showed an increased occurrence of cancer. Eisai, the manufacturer, has submitted a request to voluntarily withdraw the drug.

- The FDA is taking this action because the risks of lorcaserin outweigh its benefits based on a review of results from a randomized clinical trial assessing safety.

- Belviq/Belviq XR is indicated an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index of: 30 kg/m^2 or greater (obese), or 27 kg/m^2 or greater (overweight) in the presence of at least one weight related comorbid condition (eg, hypertension, dyslipidemia, type 2 diabetes).

- Patients should stop taking lorcaserin and talk to their healthcare provider about alternative weight-loss medicines and weight management programs. It is best to dispose of unused lorcaserin using a drug take back location.

- If a drug take back location is not available, lorcaserin can be disposed of in the household trash:

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

- The FDA is not recommending special cancer 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.

- Healthcare providers should stop prescribing and dispensing lorcaserin to patients. Healthcare providers should 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. Alternative weight-loss medicines or strategies should be discussed.

- When the FDA approved lorcaserin in 2012, the FDA required the drug manufacturer to conduct a randomized, double-blind, placebo-controlled clinical trial to evaluate the risk of cardiovascular problems. The clinical study consisted of 12,000 men and women who were overweight or obese.

    - There was a numerical imbalance in the number of patients with malignancies, with one additional cancer observed per 470 patients treated for one year.
    - More patients taking lorcaserin (n = 462; 7.7%) were diagnosed with cancer vs. placebo (n = 423; 7.1%). 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.

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— The primary safety analysis showed no meaningful difference between lorcaserin and placebo in the risk of major adverse cardiovascular events, demonstrating noninferiority (HR = 1.005, 95% CI: 0.842, 1.198).