Belviq®, Belviq XR® (lorcaserin) – Safety update

- On January 14, 2020, the FDA announced that results from a clinical trial assessing safety show a possible increased risk of cancer with the weight management medicine Belviq, Belviq XR (lorcaserin).
    - The cause of the cancer is uncertain, and the FDA cannot conclude that lorcaserin contributes to the cancer risk.
- Belviq and Belviq XR are approved as 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).
- To approve Belviq and Belviq XR, a randomized, double-blind, placebo-controlled clinical trial to evaluate the risk of heart-related problems was required by the FDA.
    - In this trial, which was conducted in approximately 12,000 participants over 5 years, more patients taking lorcaserin were diagnosed with cancer compared to patients taking placebo.
- Health care professionals should consider if the benefits of taking lorcaserin are likely to exceed the potential risks when deciding whether to prescribe or continue patients on lorcaserin.
- Patients currently taking lorcaserin should talk to their health care professionals about the potential increased risk of cancer with use of lorcaserin in order to make the best decision about their medical treatment.
- The FDA is continuing to evaluate the clinical trial results and will communicate its final conclusions and recommendations when their review is completed.