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Special Topics: Lorcaserin Approved for Weight Loss

The Food and Drug Administration recently approved the first drug for weight loss in more than ten years. Lorcaserin will be marketed by Arena Pharmaceuticals as the brand name, *Belviq*. Phentermine and fenfluramine, components of the weight loss combination, fen-phen, are nonselective serotonin agonists. Locaserin differs by selectively stimulating serotonin 2C receptors. This is believed to lead to appetite suppression. Fenfluramine was withdrawn from the U.S. market in 1997 due to an association with adverse cardiac effects in patients using it for weight loss. It was believed this was related to stimulation of the serotonin 2B receptors. Lorcaserin's selectivity for the 2C serotonin receptor is hoped to alleviate this problem.

In the BLOOM trial, nearly 3200 patients received either lorcaserin or placebo for approximately two years. The average baseline weight of patients in each group was 220 lbs. Outcome measures included weight loss at one year, weight maintained at two years and development of valvular disease of the heart. All study patients received diet and exercise counseling.

Patients were randomized to either lorcaserin or placebo at study initiation. Those in the lorcaserin group took 10 mg twice daily before meals for one year. After the first year, lorcaserin patients were re-randomized to either the study drug or placebo while those patients who took placebo the first year remained on it.

At the end of the first year, nearly 48% of patients taking lorcaserin had lost more than 5% of their body weight while only 20% of placebo patients reached this goal. Patients' average body weight decreased from 220 lbs to 206 lbs in lorcaserin patients and 215.6 lbs in the placebo group. Approximately 22% of lorcaserin patients and nearly 8% of placebo patients lost at least 10% of their body weight. Almost 68% of patients on lorcaserin were able to maintain weight loss through year two compared to just over 50% of placebo patients.

Significant decreases in cholesterol levels were noted after the first year of the study in both groups, but had increased by the end of year two. Blood glucose, A1c and insulin levels decreased in the lorcaserin group, but had increased as well at the end of year two. Blood pressure decreased significantly after both years in the lorcaserin group.

Side effects noted in patients taking lorcaserin included headache, dizziness, upper respiratory infections and nausea. There was no statistically significant valvular disease reported in lorcaserin patients during the study.

Recommended dosing for lorcaserin according to the prescribing information is 10 mg twice daily. The medication should be stopped after 12 weeks if the patient has not reached at least a 5% loss in body weight. The use of lorcaserin is contraindicated during pregnancy and should not be used in children or women who are breastfeeding. Though the BLOOM trial did not show a statistically significant incidence of depression, the prescribing information recommends monitoring patients for signs of depression.

Continued on next page

Continued from previous page

Due to lorcaserin's effects on serotonin receptors, it is not recommended for use in patients who are taking other serotonin drugs including SSRIs like fluoxetine, SNRIs like venlafaxine, MAOIs, triptans, bupropion or St. John's Wort. Patients with diabetes should be monitored for low blood sugar while men taking lorcaserin should be monitored for priapism. Also, lorcaserin can increase prolactin levels which may result in galactorrhea.

Lorcaserin represents a potential adjunct to diet and exercise in the treatment of patients who are overweight or obese. Dramatic weight loss should not be expected as a result of the medication alone, but may help 'kick-start' people who are struggling with weight management. Long-term weight maintenance once the medication been stopped has not yet been studied.

At this time, lorcarserin does not appear to have any effect on heart valves. However, until more long-term data and post-marketing studies are available, it's recommended to use cautiously in patients with heart failure or current valvular disorders.

References

Smith, S.R. et al. Multi-Center Placebo-Controlled Trial of Lorcaserin for Weight Management. N Engl J Med 2010;363:245-56.

FDA Announces Withdrawal Fenfluramine and Dexfenfluramine. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm179871.htm. Accessed June 30, 2012.

Belviq Prescribing Information. Arena Pharmaceuticals, Zofingen, Switzerland. Distributed by Eisai Inc, Woodcliff Lake, NJ. 06/2012.

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