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FDA NEWS RELEASE

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FDA Approves Belviq To Treat Some Overweight Or Obese Adults

The U.S. Food and Drug Administration today approved Belviq (lorcaserin hydrochloride), as an addition to a reduced-calorie diet and exercise, for chronic weight management.

The drug is approved for use in adults with a body mass index (BMI) of 30 or greater (obese), or adults with a BMI of 27 or greater (overweight) and who have at least one weight-related condition such as high blood pressure (hypertension), type 2 diabetes, or high cholesterol (dyslipidemia).

BMI, which measures body fat based on an individual's weight and height, is used to define the obesity and overweight categories. According to the Centers for Disease Control and Prevention, more than one-third of adults in the United States are obese.

"Obesity threatens the overall well being of patients and is a major public health concern," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "The approval of this drug, used responsibly in combination with a healthy diet and lifestyle, provides a treatment option for Americans who are obese or are overweight and have at least one weight-related comorbid condition."

Belviq works by activating the serotonin 2C receptor in the brain. Activation of this receptor may help a person eat less and feel full after eating smaller amounts of food.

The safety and efficacy of Belviq were evaluated in three randomized, placebo-controlled trials that included nearly 8,000 obese and overweight patients, with and without type 2 diabetes, treated for 52 to 104 weeks. All participants received lifestyle modification that consisted of a reduced calorie diet and exercise counseling. Compared with placebo, treatment with Belviq for up to one year was associated with average weight loss ranging from 3 percent to 3.7 percent.

About 47 percent of patients without type 2 diabetes lost at least 5 percent of their body weight compared with about 23 percent of patients treated with placebo. In people with type 2 diabetes, about 38 percent of patients treated with Belviq and 16 percent treated with placebo lost at least 5 percent of their body weight. Belviq treatment was associated with favorable changes in glycemic control in those with type 2 diabetes. The approved labeling for Belviq recommends that the drug be discontinued in patients who fail to lose 5 percent of their body weight after 12 weeks of treatment, as these patients are unlikely to achieve clinically meaningful weight loss with continued treatment.

Belviq should not be used during pregnancy. Treatment with Belviq may cause serious side effects, including serotonin syndrome, particularly when taken with certain medicines that increase serotonin

levels or activate serotonin receptors. These include, but are not limited to, drugs commonly used to treat depression and migraine. Belviq may also cause disturbances in attention or memory.

In 1997, the weight-loss drugs fenfluramine and dexfenfluramine were withdrawn from the market after evidence emerged that they caused heart valve damage. This effect is assumed to be related to activation of the serotonin 2B receptor on heart tissue. When used at the approved dose of 10 milligrams twice a day, Belviq does not appear to activate the serotonin 2B receptor.

Heart valve function was assessed by echocardiography in nearly 8,000 patients in the Belviq development program. There was no statistically significant difference in the development of FDA-defined valve abnormalities between Belviq and placebo-treated patients. Because preliminary data suggest that the number of serotonin 2B receptors may be increased in patients with congestive heart failure, Belviq should be used with caution in patients with this condition. Belviq has not been studied in patients with serious valvular heart disease.

The drug's manufacturer will be required to conduct six postmarketing studies, including a long-term cardiovascular outcomes trial to assess the effect of Belviq on the risk for major adverse cardiac events such as heart attack and stroke.

The most common side effects of Belviq in non-diabetic patients are headache, dizziness, fatigue, nausea, dry mouth, and constipation, and in diabetic patients are low blood sugar (hypoglycemia), headache, back pain, cough, and fatigue.

Belviq is manufactured by Arena Pharmaceuticals GmbH of Zofingen, Switzerland, and distributed by Eisai Inc. of Woodcliff Lake, N.J.