

NEW ENGLAND JOURNAL OF MEDICINE PUBLISHES RESULTS OF TWO-YEAR BLOOM TRIAL SHOWING LORCASERIN CAUSED SIGNIFICANT WEIGHT LOSS AND IMPROVED MAINTENANCE OF WEIGHT LOSS

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai"), together with its U.S. subsidiary Eisai Inc. and Arena Pharmaceuticals, Inc. announced today that the results from the two-year BLOOM (**B**ehavioral modification and **L**orcaserin for **O**verweight and **O**besity **M**anagement) trial with lorcaserin will be published in the July 15, 2010, issue of the *New England Journal of Medicine*. Lorcaserin is a novel obesity and weight management drug. Arena Pharmaceuticals GmbH, a wholly owned subsidiary of Arena Pharmaceuticals, Inc. has granted Eisai Inc. exclusive rights to market and distribute lorcaserin in the United States. The data presented in the article show that lorcaserin caused statistically significantly greater weight loss and improved maintenance of weight loss compared to placebo. Lorcaserin also improved values for biomarkers that may be predictive of future cardiovascular events, including lipid levels, insulin resistance, levels of inflammatory markers and blood pressure.

The BLOOM trial was a double-blind, randomized, placebo-controlled trial conducted in 3,182 obese and overweight patients. During Year 1 of the trial, the proportion of patients achieving at least 5 percent body weight loss in the lorcaserin group (47.5 percent) was more than twice that achieved by the placebo group (20.3 percent). Nearly three times as many patients achieved at least 10 percent weight loss in the lorcaserin group (22.6 percent) than in the placebo group (7.7 percent). Lorcaserin patients who completed the trial lost 8.2 percent of the body weight, or approximately 8.2 kilograms, as compared to 3.2 percent, or approximately 3.2 kilograms, in the placebo group. In Year 2, patients who continued to take lorcaserin were significantly better able to maintain their Year 1 weight loss compared to those who were switched to placebo. Lorcaserin also caused significant decreases in waist circumference, BMI, glycemic parameters, high-sensitivity C-reactive protein, and fibrinogen levels compared to placebo. Total cholesterol, LDL cholesterol and triglyceride levels at Year 1 were also significantly lower in the lorcaserin group than in the placebo group. Lorcaserin did not increase heart rate or blood pressure; rather, heart rate, systolic blood pressure and diastolic blood pressure decreased slightly.

Among the most frequent adverse events reported with lorcaserin were headache (lorcaserin vs. placebo; 18.0 percent vs. 11.0 percent); dizziness (8.2 percent vs. 3.8 percent); and nausea (7.5 percent vs. 5.4 percent). The rates of serious adverse events were the same in both groups. The rates of depression and incidence of anxiety and suicidal thoughts were low in both treatment groups. Lorcaserin caused no significant increase compared to the placebo in the incidence of new cardiac valvulopathy.

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As part of its human health care (*hhc*) mission, Eisai is committed to increasing the benefits to patients and their families by addressing unmet medical needs. Lorcaserin will not only provide Eisai with an opportunity to provide patients with a new obesity treatment option, it will also enable the Company to make further contributions for the medical management of obesity.

[Please refer to the following notes for further information on the BLOOM Trial]

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[Notes to editors]

1. **About the BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) Trial**
BLOOM, the first of three lorcaserin Phase III trials, is a double blind, randomized, placebo-controlled trial involving 3,182 patients in 98 sites in the United States. The trial evaluated 10mg lorcaserin dosed twice daily versus placebo over a two-year treatment period in obese patients with or without co-morbid conditions and overweight patients with at least one co-morbid condition, such as hypertension, cardiovascular diseases or glucose intolerance. All patients received diet and exercise counseling, and the trial did not include any dose titration or glucose intolerance. All patients were randomized in a 1:1 ratio to lorcaserin or placebo at baseline. At Week 52, 856 patients taking lorcaserin were re-randomized in a 2:1 ratio to continue lorcaserin or switch to placebo, and 697 patients on placebo were continued on placebo. Patients underwent echocardiography at screening, and at 6, 12, 18, and 24 months after initiating dosing in the trial; patients with pre-existing valvulopathy were excluded from enrolling in the trial.