No.10-63

November 10, 2010
Eisai Co., Ltd.

LORCASERIN PHASE 3 CLINICAL TRIAL IN PATIENTS WITH TYPE 2 DIABETES SHOWS STATISTICALLY SIGNIFICANT WEIGHT LOSS

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today top-line results which demonstrate that lorcaserin, a potential treatment for the management of obesity that is the subject of an exclusive U.S. marketing and supply agreement between Eisai and Arena Pharmaceuticals, Inc. (Headquarters: California, the United States, President & CEO Jack Lief, "Arena"), helped obese and overweight patients with type 2 diabetes achieve statistically significant weight loss in the one-year BLOOM-DM Phase 3 clinical trial.

The BLOOM-DM study evaluated 604 obese and overweight patients with type 2 diabetes. Patients were randomized to lorcaserin 10 mg BID (N=256), lorcaserin 10 mg dosed once daily (QD) (N=95) or placebo (N=253). At baseline, patients had an average Body Mass Index (BMI) of 36, weight of 103.6kg, age of 53 years and HbA1c of approximately 8%.

The three primary efficacy endpoints at Week 52 were as follows: the proportion of patients who lose at least 5% of their baseline body weight; change from baseline in body weight; and the proportion of patients who lose at least 10% of their baseline body weight. Using Modified Intent-to-Treat Last Observation Carried Forward (MITT-LOCF) analysis, lorcaserin 10 mg BID met the three primary efficacy endpoints by producing statistically significant weight loss compared to placebo ($p<0.0001$). At Week 52, 37.5% of patients treated with lorcaserin 10 mg BID achieved at least 5% weight loss, more than double the 16.1% of patients taking placebo. Patients treated with lorcaserin 10 mg BID achieved mean weight loss of 4.5% (4.7 kg), compared to 1.5% (1.6 kg) for placebo. Also, at Week 52, 16.3% of lorcaserin 10 mg BID patients achieved at least 10% weight loss, compared to 4.4% of patients taking placebo.

BLOOM-DM also evaluated multiple secondary endpoints at Week 52. Five families of endpoints have been or are being evaluated: glycemic, lipid, blood pressure, body composition, and Quality of Life (QOL). Data from the first three families are available, and analysis of body composition and QOL are pending. Within the glycemic, lipid and blood pressure families, lorcaserin patients achieved statistically significant improvements relative to placebo in HbA1c and fasting glucose. Lorcaserin 10 mg BID patients achieved a 0.9% reduction in HbA1c, compared to a 0.4% reduction for the placebo group ($p<0.0001$). At Week 52, changes with lorcaserin treatment relative to placebo for fasting insulin, triglycerides, total cholesterol, HDL cholesterol, LDL cholesterol, and systolic and diastolic blood pressure were not statistically significant.

The most frequent adverse events occurring in greater than or equal to 10% of patients (excluding hypoglycemia) in the lorcaserin 10 mg BID and placebo were headache, upper respiratory infection, back pain and nasopharyngitis. Headache and hypoglycemia were the only adverse events that exceeded the placebo rate by greater than 4% of patients. Adverse events of "hypoglycemia," which included asymptomatic low blood glucose measurements and symptomatic events, were reported by 29.3% and

21.0% of lorcaserin 10 mg BID and placebo patients, respectively; however, no events of severe hypoglycemia were reported in either treatment group. Serious adverse events were infrequent. Discontinuations for adverse events were 8.6% for lorcaserin 10 mg BID patients and 4.3% for placebo patients.

These top-line results, which demonstrated that diabetic patients achieved weight loss and improved glycemic parameters, provide additional support for lorcaserin's benefit-risk profile. Eisai and Arena will continue to work closely with the FDA to bring a new obesity treatment option to market and remain committed to making further contributions to the medical management of obesity.

[Please refer to the following notes for a glossary of terms]

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

Glossary of Terms

1. HbA1c (Glycohemoglobin)

Hypoglycemia that occurs over a long period of time causes excess blood glucose to bind to proteins produced by the body. Glycohemoglobin (HbA1c) is the substance that is formed when hemoglobin (Hb), a protein in red blood cells, attaches to glucose (blood sugar). HbA1c is closely associated with diabetes and is a person's average blood sugar level over the past one to one and half months. HbA1c tests measure blood sugar metabolism and are essential in controlling diabetes. HbA1c results are expressed as a percentage of total hemoglobin. An HbA1c of 4.3 to 5.8 is considered normal, while an HbA1b above 6.5 is a criterion for diagnosing diabetes.

2. MITT-LOCF (Modified Intent-to-Treat Last Observation Carried Forward) Analysis

MITT-LOCF (Modified Intent-to-Treat Last Observation Carried Forward) Analysis is an analysis method used to measure a drug's efficacy. It uses data from subjects who have been administered at least one dose of their assigned drug and have been weighed at least once following administration. For subjects who discontinued treatment part way through the trial, their latest recorded weight was used. This is known as last observation carried forward.