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Eisai Co., Ltd.

## **CARDIOVASCULAR OUTCOMES TRIAL OF ANTI-OBESITY AGENT LORCASERIN TO CONTINUE BASED ON RECOMMENDATION OF INDEPENDENT DATA MONITORING COMMITTEE AFTER COMPLETION OF INTERIM SAFETY ANALYSIS**

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") has announced that it has received a recommendation from an independent Data Monitoring Committee to continue the ongoing Cardiovascular Outcomes Trial (CAMELLIA-TIMI61 Study) of lorcaserin hydrochloride (U.S. brand name: BELVIQ®, "lorcaserin") after the completion of a pre-specified interim safety analysis, evaluating the incidence of Major Adverse Cardiovascular Events (MACE), defined as cardiovascular death, myocardial infarction or stroke. Based on this recommendation, Eisai will continue the study as planned. Topline results for this study are expected in FY 2018.

This Phase IIIb/IV clinical study, comprised of 12,000 patients, is being conducted over a 5-year period in partnership with the Thrombolysis in Myocardial Infarction (TIMI) Study Group and is intended to address the post-marketing requirement from the U.S. Food and Drug Administration to evaluate the long-term cardiovascular safety of lorcaserin.

Lorcaserin has been marketed under the brand name BELVIQ in the United States since June 2013 as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes).

Through BELVIQ, Eisai continues to make further contributions to address unmet medical needs in the clinical management of obesity and increase the benefits for patients and their families.

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**[Notes to editors]**

**1. About lorcaserin hydrochloride (U.S. brand name: BELVIQ, once daily formulation U.S. brand name: BELVIQ XR)**

Discovered and developed by Arena Pharmaceuticals, Inc. (Headquarters: California, United States, President and CEO: Amit D. Munshi), lorcaserin is a novel chemical entity that is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C receptors in the brain. Activation of these receptors may help a person eat less and feel full after eating smaller amounts of food. Lorcaserin was approved in June 2012 by the FDA 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 (BMI) of 30 kg/m<sup>2</sup> or greater (obese) or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition, and was launched in the United States under the brand name BELVIQ in June 2013 after receiving a final scheduling designation from the U.S. Drug Enforcement Administration (DEA). In addition, lorcaserin has been made available in South Korea via a third-party distributor from 2015. Lorcaserin was approved in Mexico in July 2016 and in Brazil in December 2016, with the same indication as for the United States.

Furthermore, BELVIQ XR, a once-daily formulation of lorcaserin aiming to increase convenience of administration for patients, was approved in the United States in July 2016.

In January 2017, Eisai acquired all of Arena's rights to develop and market BELVIQ.

The most common adverse reactions observed in multiple Phase III clinical studies on lorcaserin were headache, dizziness, fatigue, nausea, dry mouth and constipation in patients without diabetes, and hypoglycemia, headache, back pain, cough and fatigue in patients with diabetes. For further information on lorcaserin in the United States, including Important Safety Information (ISI), please visit the BELVIQ product website (<http://www.belviq.com>).

**2. About Cardiovascular Outcomes Trials, CAMELLIA-TIMI61 Study**

The CAMELLIA (Cardiovascular And Metabolic Effects of Lorcaserin In Overweight And Obese Patients) TIMI 61 study is the largest ongoing double-blind, placebo-controlled, parallel-group Phase IIIB/IV study among weight loss medications. The primary safety objective is to evaluate the incidence of major adverse cardiovascular events (MACE), defined as cardiovascular death, myocardial infarction or stroke. If the primary safety objective is met, the efficacy objective is to evaluate the impact of lorcaserin on the incidence of MACE+, defined as MACE or hospitalization due to unstable angina or heart failure, or any coronary revascularization. In addition, other secondary objectives include the evaluation of lorcaserin on glycemic control in patients with type 2 diabetes mellitus and the potential to delay or prevent the conversion from pre-diabetes to type 2 diabetes.

**3. About the TIMI Study Group**

The TIMI Study Group is an Academic Research Organization based at Brigham and Women's Hospital that has been leading practice-changing cardiovascular clinical trials for 30 years.