

**EISAI ANNOUNCES TOP-LINE RESULTS OF INVESTIGATIONAL STUDY  
ON COADMINISTRATION OF LORCASERIN AND PHENTERMINE**  
*Trial Supports Safety and Tolerability After 12 Weeks of Treatment*

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that an investigational study of its antiobesity drug lorcaserin hydrochloride (U.S. brand name: BELVIQ®; "lorcaserin") when coadministered with phentermine hydrochloride ("phentermine") jointly conducted by its U.S. subsidiary Eisai Inc. and Arena Pharmaceuticals, Inc. (Headquarters: California, United States; President & CEO: Jack Lief, "Arena") met its primary safety objective. The results of the study demonstrate that the short-term combination of lorcaserin plus phentermine does not appear to be associated with an exacerbation in the proportion of pre-specified adverse events compared to therapy with lorcaserin alone. The detailed results of the trial are to be presented at ObesityWeek2014 which is the Annual Meeting of The Obesity Society and the American Society for Metabolic and Bariatric Surgery held in Boston from November 2 to 7, 2014.

The coadministration of lorcaserin and phentermine for weight management is investigational. The efficacy and safety of coadministration of lorcaserin and other weight loss products such as phentermine have not been established. The study was a randomized, double-blind study of 12-weeks duration in 238 overweight and obese adult patients designed to evaluate whether treatment with lorcaserin plus phentermine is associated with exacerbation of potential serotonergic adverse events compared to lorcaserin alone. Patients were randomized 1:1:1 to one of three treatment arms consisting of either lorcaserin alone (10 mg twice daily), lorcaserin (10 mg twice daily) with phentermine (15 mg once daily) or lorcaserin (10 mg twice daily) with phentermine (15 mg twice daily). In addition, patients received standardized weight-loss counseling throughout the trial.

The objective of the trial was to assess the proportion of subjects reporting at least one of nine common potential serotonergic adverse events (headache, dizziness, nausea, fatigue, dry mouth, diarrhea, vomiting, insomnia, and/or anxiety) from baseline to the end of treatment. The most common adverse events that occurred during the trial were headache, fatigue, insomnia, dizziness, dry mouth and constipation.

Through lorcaserin, Eisai is committed to making further contributions to address unmet medical needs that exist in the clinical management of obesity.

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

## **[Notes to editors]**

### **1. About BELVIQ (lorcaserin hydrochloride)**

Discovered and developed by Arena Pharmaceuticals, Inc., lorcaserin hydrochloride (U.S. brand name: BELVIQ; “lorcaserin”) is a new 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. BELVIQ was approved in June 2012 by the U.S. Food and Drug Administration (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 co-morbid condition, and was launched in the United States in June 2013 after receiving a final scheduling designation from the U.S. Drug Enforcement Administration (DEA).

In addition, the original agreement, granting Eisai exclusive rights to market and distribute lorcaserin in 21 countries throughout the Americas, was expanded in November 2013 to include most countries and territories worldwide, most notably the European Union, Japan and China (excluding South Korea, Taiwan, Australia, New Zealand and Israel). 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 BELVIQ, including Important Safety Information (ISI), please visit the BELVIQ product website (<http://www.belviq.com>).

### **2. About Worldwide Overweight and Obesity**

In recent years, obesity has become a major global health problem, with more than 1.4 billion adults worldwide believed to be overweight and approximately 500 million of that number qualifying as obese. By region, around 170 million people in the United States and 150 million people in Europe are reported to fall into one or both categories, while in Asia, the overweight and obese population includes an estimated 100 million people in China and a further 25 million people in Japan.

### **3. About Phentermine**

Phentermine (generic name) is an appetite suppressant approved by the U.S. Food and Drug Administration (FDA) in 1959 that stimulates the release of norepinephrine and dopamine in the brain. It is indicated for the short term treatment of obesity, and is widely used as an antiobesity drug in the United States.