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Eisai Co., Ltd.

# U.S. FDA APPROVES ANTIOBESITY AGENT BELVIQ® (lorcaserin HCl) for Adults

*First Prescription Weight-Loss Treatment Approved in U.S. in 13 Years*

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that Arena Pharmaceuticals, Inc. (Headquarters: California, the United States, President & CEO: Jack Lief, "Arena") received approval from the U.S. Food and Drug Administration (FDA) on June 27, 2012 (local U.S. time) for BELVIQ® (pronounced BEL-VEEK) 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$^2$ or greater, or 27 kg/m$^2$ or greater in the presence of at least one weight related comorbid condition. BELVIQ is the first prescription weight-loss treatment approved in the United States in 13 years.

According to the U.S. Centers for Disease Control and Prevention, over two thirds of adults in the U.S. are either overweight or obese, with the percentage of obese people more than doubling (from approx. 15% to 36%) between 1980 and 2010. Being obese or overweight may be accompanied by other comorbid conditions such as diabetes, hyperlipidemia and hypertension, with the increase in the obese and overweight population constituting a major social problem.

The approval of BELVIQ will enable Eisai to provide a new treatment option in the field of obesity management, an area in which there are significant unmet medical needs. Eisai Inc., Eisai's U.S. subsidiary, will be responsible for marketing and distributing the drug in the U.S., while Arena will handle the manufacturing and supply of the finished product.

Discovered and developed by Arena, BELVIQ is a serotonin receptor agonist that works by selectively activating the serotonin 2C receptor in the brain and is believed to suppress food intake and promote weight loss. Three double-blind, randomized, placebo-controlled trials demonstrated that BELVIQ along with diet and exercise was more effective than diet and exercise alone at helping patients lose 5% or more of body weight after one year and managing the weight loss for up to two years.

BELVIQ will be launched following a review by the U.S. Drug Enforcement Administration (DEA) to determine final scheduling designation based on the U.S. Controlled Substances Act. As part of the approval of BELVIQ, Eisai and Arena have committed to conducting additional post-marketing clinical studies to assess the safety and efficacy of BELVIQ for weight management in obese pediatric patients, as well as to evaluate the effect of long-term treatment with BELVIQ on the incidence of major adverse cardiovascular events in overweight and obese patients with cardiovascular disease or multiple cardiovascular risk factors. The cardiovascular outcome trial will include echocardiographic assessments.

Eisai will provide BELVIQ as a new treatment option for weight management and make further contributions in the medical management of obesity as it seeks to carry out its commitment to address unmet medical needs and increase the benefits it provides to patients and their families as part of its *human health care (hhc)* mission.

**[Please refer to the following notes for further information on BELVIQ, the Phase III Clinical Trial Program and Arena Pharmaceuticals]**

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**[Notes to editors]**

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

BELVIQ®, discovered and developed by Arena, is a new chemical entity that is believed to act as a selective serotonin 2C (5-HT2C) receptor agonist. The 5-HT2C receptor is expressed in the brain, including the hypothalamus, an area believed to be involved in the control of appetite and metabolism. Stimulation of the 5-HT2C receptor is reported to be strongly associated with reduction in food intake and increasing meal-related satiety. BELVIQ was approved by the FDA for the following indications.

**【Indications and Usage of BELVIQ】**

BELVIQ is indicated to be used along with a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30kg/$m^2$ or greater, or
- 27kg/$m^2$ or greater in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes)

Limitations of Use:

- The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established
- The effect of BELVIQ on cardiovascular morbidity and mortality has not been established

In July 2010, Eisai's U.S. subsidiary Eisai Inc. entered into an exclusive U.S. marketing and supply agreement for BELVIQ with Arena Pharmaceuticals GmbH, the Swiss subsidiary of Arena. This agreement was amended in May 2012 to expand the licensed territories to include 20 countries throughout the Americas, including Mexico, Brazil and Canada, in addition to the United States.

**2. About BELVIQ® Phase III Clinical Trial Program**

The BELVIQ® Phase III clinical trial program consisted of three double-blind, randomized, placebo-controlled trials, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management), BLOSSOM (Behavioral modification and LOrcaserin Second Study for Obesity Management) and BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus), and enrolled approximately 7,800 patients. All three trials included a standardized program of diet, moderate exercise and behavioral counseling for both the placebo and BELVIQ groups.

BLOOM and BLOSSOM evaluated the safety and efficacy of BELVIQ versus placebo in non-diabetic, obese (BMI of 30 to 45kg/$m^2$) adult patients (18-65 years old) and non-diabetic overweight (BMI 27 to 29.9kg/$m^2$) patients who have at least one weight-related co-morbid condition. BLOOM evaluated BELVIQ versus placebo in 3,182 patients over a two-year treatment period, while BLOSSOM evaluated BELVIQ versus placebo in 4,008 patients over a one-year treatment period. In both the BLOOM and BLOSSOM trials, BELVIQ produced statistically significant and clinically meaningful weight loss compared to placebo. The most common adverse events (greater than 5% and more commonly than with placebo) in these trials were headache, dizziness, fatigue, nausea, dry mouth, and constipation. Pooled data from BLOOM and BLOSSOM were presented at the American Diabetes Association's 70th Scientific Sessions in June 2010. BLOOM data was also published in the July 15, 2010 issue of the *New England Journal of Medicine*.

BLOOM-DM evaluated BELVIQ versus placebo in 604 obese and overweight adult patients with type 2 diabetes. The top-line results of the trial, which demonstrated that BELVIQ helped obese and overweight patients with type 2 diabetes achieve statistically significant weight loss, were announced by Arena on November 9, 2010.

The most common adverse events (greater than 5% and more commonly than with placebo) were hypoglycemia, headache, back pain, cough, and fatigue.

**3. About Arena Pharmaceuticals, Inc.**

Arena Pharmaceuticals, Inc. is a biopharmaceutical company focused on discovering, developing and commercializing oral drugs that target G protein-coupled receptors, an important class of validated drug targets, in four major therapeutic areas: cardiovascular, central nervous system, inflammatory and metabolic diseases. Arena Pharmaceuticals® and Arena® are registered service marks of the company. BELVIQ® is a registered trademark of Arena Pharmaceuticals GmbH.