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# ARENA SUBMITS RESPONSE TO FDA COMPLETE RESPONSE LETTER FOR LORCASERIN

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that Arena Pharmaceuticals, Inc. (Headquarters: California, United States, President & CEO: Jack Lief, "Arena") has submitted its response to the Complete Response Letter (CRL) issued by the U.S. Food and Drug Administration (FDA) following review of the lorcaserin (generic name) New Drug Application (NDA).

Lorcaserin, which Arena discovered and has developed, is intended for weight management, including weight loss and maintenance of weight loss, in patients who are obese (Body Mass Index, BMI≥30) or patients who are overweight (BMI≥27) and have at least one weight-related co-morbid condition. Lorcaserin is the subject of an exclusive licensing agreement concluded between Eisai's U.S. Subsidiary Eisai Inc. and Arena Pharmaceuticals GmbH, the wholly-owned Swiss subsidiary of Arena concerning its marketing and supply in the United States.

The response submitted by Arena is intended to address the FDA's requests as outlined in the CRL, which includes data from the Phase 3 BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial, which evaluated lorcaserin for weight loss in patients with type 2 diabetes. The response also includes data and analyses from activities conducted to investigate tumors observed in a lorcaserin rat carcinogenicity study.

It is anticipated that the FDA will confirm its acceptance and assign a new Prescription Drug User Fee Act (PDUFA) date.

[Please refer to the following notes for information on lorcaserin, lorcaserin phase III clinical trial program overview, Arena pharmaceuticals, Inc. and the prevalence of obesity in the United States]

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## [Notes to editors]

#### 1. About Lorcaserin

Lorcaserin, which Arena discovered and has developed, is a new chemical entity that is believed to act as a selective serotonin 2C receptor agonist. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area believed to be involved in the control of appetite and metabolism.

### 2. About Lorcaserin Phase III Clinical Trial Program Overview

The lorcaserin Phase III clinical trial program consists 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.

BLOOM and BLOSSOM evaluated lorcaserin versus placebo in patients who are obese or patients who are overweight and have at least one weight-related co-morbid condition. BLOOM evaluated 3,182 patients over a two-year treatment period, and BLOSSOM evaluated 4,008 patients over a one-year treatment period. In both the BLOOM and BLOSSOM trials, lorcaserin produced statistically significant and clinically meaningful weight loss compared to placebo and was generally well tolerated. The most frequently reported adverse events in these trials were headache, upper respiratory infection, nasopharyngitis, dizziness and nausea. 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 604 obese and overweight patients with type 2 diabetes over a one-year treatment period. The top-line results of the trial, which demonstrate that lorcaserin helped obese and overweight patients with type 2 diabetes achieve statistically significant weight loss, were announced by Arena on November 9, 2010.

#### 3. About Arena Pharmaceuticals, Inc.

Arena is a clinical-stage 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<sup>®</sup> and Arena<sup>®</sup> are registered service marks of the company.

# 4. About the Prevalence of Obesity in the United States

According to the U.S. Centers for Disease Control and Prevention, two thirds of American adults are overweight or obese. Furthermore, the prevalence of obesity in the United States more than doubled (from 15% to 34%) among adults from 1980 to 2008.