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# EISAI INC. ENTERS INTO MARKETING AND SUPPLY AGREEMENT WITH ARENA PHARMACEUTICALS FOR LORCASERIN, A POTENTIAL TREATMENT FOR OBESITY AND WEIGHT MANAGEMENT

Eisai Co., Ltd. (Headquarters: Tokyo; President & CEO: Haruo Naito) announced today that its U.S. subsidiary Eisai Inc. has entered into an agreement with Arena Pharmaceuticals GmbH, a wholly-owned subsidiary of Arena Pharmaceuticals, Inc. (Headquarters: California, United States; President & CEO: Jack Lief, "Arena") for exclusive U.S. rights to commercialize lorcaserin.

A New Drug Application (NDA) for lorcaserin was submitted to the U.S. Food and Drug Administration (FDA) by Arena in December 2009. If approved, Eisai Inc. will exclusively market and distribute lorcaserin in the United States. Arena will handle the manufacture and supply of the finished commercial product at its facility in Switzerland.

Lorcaserin is a drug candidate for potential use in the treatment of obesity, including weight loss, for patients who are obese (Body Mass Index or BMI  $\geq$  30) or overweight (BMI  $\geq$  27) with at least one weight-related co-morbid condition.

Obesity is one of the most pressing public health issues in the United States today and over one-third of American adults are obese according to the U.S. Centers for Disease Control and Prevention. Furthermore, the prevalence of obesity in the United States more than doubled (from 15 percent to 34 percent) among adults from 1980 to 2008.

As part of its *human health care* (*hhc*) mission, Eisai is committed to increasing benefits to patients and their families by addressing unmet medical needs. This agreement will provide Eisai with an opportunity to bring a new obesity treatment option to market. Additionally, it will enable the company to create strong synergy in its existing gastrointestinal franchise with the new product for obesity management, through which Eisai expects to make further contributions to the medical management of obesity.

# [Please refer to the following notes for product overview, clinical trial outline and company information]

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# [Notes to editors]

#### 1. About Lorcaserin

Lorcaserin is a single agent that is believed to act as a specific and selective serotonin 2C receptor agonist. The serotonin 2C receptor is expressed in the brain, including the hypothalamus, an area involved in the control of appetite and metabolism. Stimulation of the serotonin 2C receptor in the hypothalamus is associated with feeding behavior and satiety. An NDA for lorcaserin is currently under review by the FDA, which has assigned a PDUFA date of October 22, 2010. In addition, the FDA has notified Arena of the tentative scheduling of an Endocrinologic and Metabolic Drugs Advisory Committee meeting on September 16, 2010, for the review of the lorcaserin NDA.

# 2. About the Phase III Program

The NDA is based on a data package from lorcaserin's development program that includes 18 clinical trials totaling 8,576 patients. The pivotal Phase III clinical trial program, BLOOM (Behavioral modification and Lorcaserin for Overweight and Obesity Management) and BLOSSOM (Behavioral modification and Lorcaserin Second Study for Obesity Management), evaluated nearly 7,200 patients treated for up to two years. In both trials, lorcaserin produced statistically significant and clinically meaningful weight loss and was generally well tolerated. The most frequently reported adverse events in these trials were headache, upper respiratory infection, nasopharyngitis, dizziness and nausea.

These double-blind, randomized, placebo-controlled trials evaluated non-diabetic obese patients (BMI 30 to 45) with or without co-morbid conditions and non-diabetic overweight patients (BMI 27 to 29.9) with at least one co-morbid condition, such as hypertension, cardiovascular diseases or glucose intolerance.

In addition to the pivotal program, Arena is evaluating lorcaserin for weight loss in obese and overweight patients with type II diabetes in its BLOOM-DM (Behavioral modification and Lorcaserin for Overweight and Obesity Management in Diabetes Mellitus) trial. Arena plans to file the results of BLOOM-DM as a supplement to the NDA.

## 3. 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.

#### 4. BMI

BMI (Body Mass Index) = Weight (kg) / (Height (m) X Height (m))

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