No.10-48

September 17, 2010
Eisai Co., Ltd.

EISAI PROVIDES UPDATE ON LORCASERIN FDA ADVISORY COMMITTEE MEETING

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that the U.S. Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee voted 9 to 5 that the available data do not adequately demonstrate that the potential benefits of lorcaserin outweigh the potential risks, when used long-term in a population of overweight and obese individuals to allow marketing approval. Lorcaserin, a potential treatment for obesity, is currently under regulatory review in the United States.

Lorcaserin is the subject of an exclusive licensing agreement concluded between’s Eisai’s U.S. Subsidiary Eisai Inc. and Arena Pharmaceuticals GmbH, the wholly-owned Swiss subsidiary of Arena Pharmaceuticals, Inc. (Headquarters: California, United States, President & CEO: Jack Lief, “Arena”) concerning its commercialization in the United States. Discovered and developed by Arena, lorcaserin 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.

Eisai believes that lorcaserin has a positive benefit-risk profile and represents a potential advance in the treatment of obesity. Arena will continue to work with the FDA as it completes review of the lorcaserin new drug application.

Although advisory committees provide recommendations to the FDA, the agency makes the final decisions. The FDA has assigned a PDUFA date, the target date for the agency to complete its review of the lorcaserin New Drug Application (NDA) of October 22, 2010.

As part of its human health care (*hhc*) mission, Eisai is committed to increasing the benefits to patients and their families by addressing unmet medical needs. Lorcaserin will not only provide Eisai with an opportunity to provide patients with a new obesity treatment option, it will also enable the Company to make further contributions for the medical management of obesity.

[Please refer to the following notes for further information on the lorcaserin NDA and lorcaserin]

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

[Notes to editors]

1. Lorcaserin New Drug Application

The lorcaserin new drug application 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.

2. About Lorcaserin

Lorcaserin is a new chemical entity 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 believed to be involved in the control of appetite and metabolism. Arena has patents that cover lorcaserin in the United States and other jurisdictions, which in most cases are capable of continuing into 2023 without taking into account any patent term extensions or other exclusivity Arena might obtain.