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Eisai Co., Ltd.

## **U.S. FDA Accepts Resubmission of Lorcaserin New Drug Application**

***-- FDA Target Action Date Set for June 27, 2012 --***

Eisai Co., Ltd.'s U.S. subsidiary Eisai Inc. and Arena Pharmaceuticals, Inc. ("Arena") announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing and review Arena's resubmission of the New Drug Application (NDA) for lorcaserin. The FDA has categorized it as a Class 2 resubmission, and assigned a new Prescription Drug User Fee Act (PDUFA) target date of June 27, 2012.

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

Arena submitted the original NDA for lorcaserin in December 2009, and the FDA issued a Complete Response Letter (CRL) in October 2010. Arena submitted a response to the lorcaserin CRL in December 2011.

For more information about the response to CRL, visit <http://www.eisai.com/news/news201201.html>.

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