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Lorcaserin receives positive vote from FDA advisory committee

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Singapore:Ã?Â Eisai announced that the US Food and Drug Administration (FDA) Endocrinologic and Metabolic Drugs Advisory Committee voted 18 to four, with one abstention, at a meeting held on May 10, 2012 that the available data adequately demonstrate that the potential benefits of the anti-obesity agent lorcaserin outweigh the potential risks when used long-term in a population of overweight and obese individuals. Currently under regulatory review in the United States, lorcaserin is an investigational drug candidate that was discovered and is being developed by US-based Arena Pharmaceuticals.

Lorcaserin is intended for weight management, including weight loss and maintenance of weight loss, in patients who are obese (BMIÃ?Â¢Ã¢â?¬Â°Ã?Â¥30) or patients who are overweight (BMIÃ?Â¢Ã¢â?¬Â°Ã?Â¥27) and have at least one weight-related co-morbid condition. Lorcaserin in the subject of an exclusive US marketing and supply agreement concluded between Eisai's US subsidiary Eisai and Arena Pharmaceuticals GmbH, the wholly-owned Swiss subsidiary of Arena.

According to the US 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 approximately 15 percent to approximately 36 percent) among adults from 1980 to 2010.

The results of the vote mean that the advisory committee supports lorcaserin as a potential new treatment option for the medical management of overweight and obese patients. Although advisory committees provide recommendations to the FDA, the agency makes the final decisions regarding approval. The Prescription Drug User Fee Act (PDUFA) date for the lorcaserin New Drug Application (NDA) resubmission is June 27, 2012, which is the target date for the agency to complete its review.